

EXHIBIT 508

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 MDL NO: 1968

5 IN RE: DIGITEK PRODUCT LIABILITY
6 LITIGATION,
7 _____ /

8
9 100 N. Tampa Street
10 Suite 2900
11 Tampa, FL 33602
12 February 18, 2011
13 at 8:15 a.m.

14 VIDEOTAPE DEPOSITION OF DAVID BLIESNER, Ph.D.

15
16
17 Taken on behalf of the Defendants before
18 PHILIP RYAN, RPR, Court Reporter, Notary Public in
19 and for the State of Florida at Large, pursuant to
20 Defendant's Notice of Taking Deposition in the
21 above cause.
22
23
24
25

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 2		Page 4	
1	APPEARANCES:	1	THE VIDEOGRAPHER: We're on the 08:15
2	MIKE KERENSKY, ESQUIRE	2	record at 8:15 a.m. The date today is 08:15
3	Williamson & Rusnak	3	February 18th of 2011. This is the videotape 08:15
4	4310 Yoakum Boulevard	4	deposition of Dr. David M. Bliesner in regard 08:15
5	Houston, TX 77006-5818	5	to the Digitek product liability litigation, 08:16
6	(713)223-3330	6	civil action MDL 1968. 08:16
7	(via telephone)	7	This videotape deposition is being held 08:16
8	Attorney for Plaintiffs	8	at 100 North Tampa, within suite 2900. The 08:16
9	MICHAEL ANDERTON, ESQUIRE	9	deposition was noticed by attorney Matt 08:16
10	Tucker, Ellis & West, LLP	10	Moriarty, I believe. 08:16
11	1150 Huntington Building	11	MR. ANDERTON: Richard Dean, actually. 08:16
12	925 Euclid Avenue	12	THE VIDEOGRAPHER: Okay. The 08:16
13	Cleveland, OH 44115	13	videographer is Alan Pokotilow and the court 08:16
14	(216)592-5000	14	reporter is Philip Ryan. At the time of 08:16
15	Attorney for Defendant Activis Totowa,	15	transcript, the tape will be archived at 08:16
16	LLC, Activis, Inc.,	16	Renillo Deposition and Discovery. 08:16
17	and Activis Elizabeth, LLC	17	Counsel, please state your name and 08:16
18	SARAH E. DREWES, ESQUIRE	18	affiliation for the record, after which our 08:16
19	Shook, Hardy & Bacon, LLP	19	court reporter will swear the witness and we 08:16
20	2555 Grand Boulevard	20	can proceed. 08:16
21	Kansas City, Missouri 64108	21	MR. ANDERTON: Michael Anderton with 08:16
22	(816)474-6550	22	Tucker Ellis & West on behalf of the Activis 08:16
23	Attorney for Mylan Pharmaceuticals,	23	Defendants. 08:16
24	Inc., Mylan Inc., Mylan Bertek	24	MS. DREWES: Sarah Drewes, with Shook, 08:16
25	Pharmaceuticals, Inc., and UDL Labs	25	Hardy & Bacon on behalf of the Mylan 08:16
	ALSO PRESENT:		
	Alan Pokotilow, videographer		
	INDEX		
	PAGE		
	DIRECT EXAMINATION:		
	BY MR. ANDERTON		
	5		
Page 3		Page 5	
1	EXHIBIT INDEX	1	Defendants. 08:16
2	MAR	2	MR. KERENSKY: Mike Kerensky for the 08:16
3	Exhibit	3	Plaintiff Mimi Vega. 08:16
4	Exhibit 145 Invoices. 94	4	MR. ANDERTON: And just so the record is 08:16
5	Exhibit 146 E-mail. 99	5	clear, Mr. Kerensky is participating by 08:17
6	Exhibit 147 Binder. 117	6	telephone. 08:17
7	Exhibit 148 Binder. 117	7	MR. KERENSKY: Correct. 08:17
8	Exhibit 149 Binder. 117	8	The Deponent herein, 08:17
9	Exhibit 150 Binder. 117	9	DAVID BLIESNER, Ph.D., 08:17
10	Exhibit 151 Notice. 122	10	Being first duly sworn to tell the truth, the 08:17
11	Exhibit 152 Notes. 123	11	whole truth, and nothing but the truth, was 08:17
12	Exhibit 153 Notes. 123	12	examined and testified as follows: 08:17
13	Exhibit 154 Binder. 161	13	DIRECT EXAMINATION 08:17
14	Exhibit 155 Binder. 337	14	BY MR. ANDERTON: 08:17
15	Exhibit 156 Binder. 337	15	Q. Good morning, Dr. Bliesner. 08:17
16		16	A. Good morning, sir. 08:17
17		17	Q. How are you? 08:17
18		18	A. Okay. 08:17
19		19	Q. Thanks for accommodating the early start 08:17
20		20	time. 08:17
21		21	A. Sure. 08:17
22		22	Q. I know it's an early day, but if we're 08:17
23		23	going to get everybody home to spend time with 08:17
24		24	their families this weekend, I thought 8 o'clock 08:17
25		25	was the best time to start. So thank you. 08:17

2 (Pages 2 to 5)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 6			Page 8		
1	A. You're welcome.	08:17	1	extra one.	08:19
2	Q. Some ground rules. I know you -- we did	08:17	2	A. I do not.	08:19
3	this about two or three weeks ago now, a little	08:17	3	Q. Okay. Well, I'm going to hand you a	08:20
4	more than three weeks ago so you're familiar with	08:17	4	copy.	08:20
5	the process, but I just want to repeat some ground	08:17	5	A. Okay.	08:20
6	rules. And if you have any questions about them,	08:17	6	Q. Mike, this is Exhibit 93.	08:20
7	kind of let me know; okay?	08:17	7	Dr. Bliesner, I have handed you a document	08:20
8	A. Okay.	08:17	8	that has been marked as Exhibit 93. Have you seen	08:20
9	Q. As you know, I'm going to ask questions,	08:17	9	that document before?	08:20
10	you're going to answer my questions. If you don't	08:17	10	A. Yes.	08:20
11	understand a question, I would ask that you tell	08:17	11	Q. It's a copy of your CV, your resume;	08:20
12	me that and ask me to rephrase it or to state it	08:18	12	correct?	08:20
13	differently; is that fair?	08:18	13	A. It is.	08:20
14	A. That is fair.	08:18	14	Q. You prepared it?	08:20
15	Q. All right. And if I ask a question and	08:18	15	A. I did.	08:20
16	you answer it without asking me to rephrase or	08:18	16	Q. Is it accurate and current?	08:20
17	restate it somehow, I will assume that you	08:18	17	A. No.	08:21
18	understood it.	08:18	18	Q. And last time you were asked -- I think	08:21
19	Is that all right?	08:18	19	that you gave some testimony that there were a	08:21
20	A. Okay.	08:18	20	couple of board memberships that had kind of	08:21
21	Q. You need to keep your voice up probably	08:18	21	changed and there were some minor changes. But as	08:21
22	just a little. I know you're mic'd and I know	08:18	22	concerns your education and work experience, is	08:21
23	from the last time that you're -- at times at	08:18	23	that CV accurate and current?	08:21
24	least are probably fairly soft-spoken. So just	08:18	24	A. No.	08:21
25	try to make sure that your voice stays elevated so	08:18	25	Q. What is not accurate or current about	08:21

Page 7			Page 9		
1	at least the mic hears it because as you know, the	08:18	1	your work experience or education as reflected on	08:21
2	proceedings are being recording by video camera	08:18	2	that CV?	08:21
3	and audio as well; all right?	08:18	3	A. Yesterday I presented a guest lecture at	08:21
4	A. Okay.	08:18	4	the University of South Florida College of	08:21
5	Q. Now, Dr. Bliesner, one more kind of key	08:18	5	Medicine.	08:21
6	point. You know, I attended the last session and	08:18	6	Q. What was the topic of that lecture?	08:21
7	I noticed as I did that, that there were what I	08:18	7	A. The topic was something to the effect	08:21
8	felt were a fair amount of occasions where you	08:19	8	"Consumer Health and GMPs."	08:21
9	didn't really respond to the questions that	08:19	9	Q. Tell me generally the substance of	08:21
10	Mr. Moriarty had asked you. And it's obvious from	08:19	10	the -- of the lecture, the subject of the lecture	08:21
11	your credentials and from your -- just -- just	08:19	11	that you gave yesterday at you said South Florida?	08:21
12	dealing with you in the last deposition that	08:19	12	A. University South Florida.	08:21
13	you're a very intelligent, very capable listener.	08:19	13	Q. University of South Florida.	08:21
14	We know that you've been told by Plaintiffs'	08:19	14	A. Yes.	08:21
15	counsel to listen very carefully. So I would ask	08:19	15	Q. Can you give me a little more detail	08:21
16	that you really do me the favor of listening and	08:19	16	than just the topic you just described?	08:21
17	making sure that when you answer a question,	08:19	17	A. Other than pulling up the course outline	08:22
18	you're actually answering the question that I ask;	08:19	18	and taking a look at it, in general it was an	08:22
19	okay?	08:19	19	overview of the drug development process and where	08:22
20	A. Okay.	08:19	20	GMPs become pertinent in the drug development	08:22
21	Q. I want to talk for a moment about your	08:19	21	process and an introduction to people who had not	08:22
22	credentials. Do you have a copy of your CV with	08:19	22	been exposed to the concepts of the GMPs, and some	08:22
23	you?	08:19	23	examples of enforcement and where they could go to	08:22
24	A. Let me check.	08:19	24	review the GMPs themselves.	08:22
25	Q. Please. And if you don't, I have an	08:19	25	Q. Drug development. Does that mean --	08:22

3 (Pages 6 to 9)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 10		Page 12	
1	well, you tell me what that means. What do you	1	A. I gave a brief overview of the drug
2	mean by drug development?	2	development process, I indicated at what point
3	A. Drug development is the process of	3	GMPs become applicable, talked about the hierarchy
4	discovering an entity that may have	4	of the law in a very general sense and where the
5	pharmacological activity and moving it to a final	5	GMPs come into play. I talked about the guidance
6	product.	6	documents and compliance program guidance manuals
7	Q. What would you characterize as the	7	that are available online on the FDA website,
8	primary target audience for that lecture?	8	what's contained generally in those documents, the
9	A. The students in the class were getting a	9	quality systems that are associated with that, and
10	masters in biotechnology.	10	the hierarchy with respect to enforcement of
11	Q. And when you talk about introduction to	11	compliance of the GMPs. Much of the course was
12	GMPs in the course or in the context of that	12	left as attachments for the students to go and
13	lecture that you gave yesterday, tell me in more	13	look in detail if they sought to.
14	detail about the types of concepts that you	14	Q. When you used term -- just to be clear,
15	presented with respect to the introduction to	15	when you used the term GMP as you did in the
16	GMPs.	16	description and the ones you gave before, that is
17	A. I would have to go back and pull up the	17	an acronym for good manufacturing practices;
18	course outline to talk explicitly about it.	18	correct?
19	Q. Well, you just did it yesterday, right,	19	A. It is.
20	Dr. Bliesner?	20	Q. And that is a subject or a topic that
21	A. Uh-huh.	21	emanates from the code of federal regulations
22	Q. You're a very smart man; right?	22	under the United States code; correct?
23	MR. KERENSKY: Michael, that's not	23	A. The GMPs are part of the code of federal
24	necessary.	24	regulations.
25	MR. ANDERTON: Mike.	25	Q. You said that you discussed -- that one
Page 11		Page 13	
1	MR. KERENSKY: I object to the form of	1	of the things you discussed was at what point GMPs
2	the question.	2	become relevant to the drug development process.
3	MR. ANDERTON: You can object and I	3	A. (The witness nodded).
4	appreciate your objection and you make your	4	Q. What is that point in your mind?
5	record obviously, but I asked him what he	5	A. In my opinion?
6	talked about yesterday. Certainly he can	6	Q. Yes.
7	remember that.	7	A. The point at which the GMPs become
8	MR. KERENSKY: Well, you certainly need	8	applicable is when you start testing the product
9	to be professional and not say things like	9	or active in people.
10	"You're smart man; right?" That's what I'm	10	Q. In people you said?
11	scolding you about.	11	A. Yes.
12	MR. ANDERTON: Your scolding is noted,	12	Q. Does that mean when you are
13	Mike.	13	participating in some sort of clinical trial?
14	MR. KERENSKY: Thank you very much.	14	A. Yes.
15	BY MR. ANDERTON:	15	Q. So GMPs in your mind aren't applicable
16	Q. Dr. Bliesner, please tell me when you	16	if you're merely doing animal or other lab
17	described a few moments ago that you gave an	17	studies; is that correct?
18	introduction to GMPs --	18	A. That is correct.
19	A. Yes.	19	Q. And when you used the term "drug
20	Q. -- as part of a presentation you made	20	development process," I assume that you're
21	yesterday.	21	talking -- and correct me if my assumption is
22	A. Yes.	22	wrong -- I assume that you're talking about a drug
23	Q. Please give me a description of the	23	or an entity as you used that term that has not
24	types of concept that you presented on with	24	yet been approved for market sale by the FDA.
25	respect to introduction to GMPs?	25	A. Not necessarily.

4 (Pages 10 to 13)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 14			Page 16				
1	Q.	Under what circumstances can a drug that	08:27	1	Q.	Describe how that works. I haven't been	08:30
2		hasn't been developed be approved by the FDA?	08:27	2		in college in a long time, so what is the current	08:30
3	A.	I don't know if I understand exactly the	08:27	3		practice with respect to distributing course	08:30
4		question you're asking.	08:27	4		materials or even a seminar like this? How do you	08:30
5	Q.	Well, you described -- you used the term	08:27	5		distribute via Internet link?	08:30
6		"drug development process" and then you clarified	08:27	6	A.	To answer your first question, I don't	08:30
7		and added substance to that term by indicating	08:27	7		know if there is a general way to do it.	08:30
8		that it was the -- the process of taking an entity	08:27	8	Q.	How did you do it?	08:30
9		from concept to production and marketing; correct?	08:27	9	A.	How did I do it? I took the	08:30
10	A.	Correct.	08:28	10		presentation -- as I told you -- from my basic	08:30
11	Q.	If your -- that process begins before	08:28	11		course material, targeted it to the needs of the	08:30
12		FDA approval; correct?	08:28	12		professor, put in a Power Point presentation,	08:30
13	A.	Drug development process is very complex	08:28	13		converted it to a PDF file so it's secure. I	08:30
14		and it's not, does not fit to one specific case.	08:28	14		created a folder up on one of my websites that was	08:30
15		For instance, if you have a generic drug you have	08:28	15		blind, I uploaded it and provided a link to the	08:30
16		to do drug development as well but it's already on	08:28	16		professor and said that the students could access	08:31
17		a product that has been approved for market. So	08:28	17		it if they'd like.	08:31
18		that could be considered drug development as well,	08:28	18	Q.	Okay. And then did you -- I assume then	08:31
19		as opposed to discovering a new entity and moving	08:28	19		that you repeated the web address for that link	08:31
20		it forward.	08:28	20		during the presentation?	08:31
21	Q.	Well, even a generic drug --	08:28	21	A.	No.	08:31
22	A.	Uh-huh.	08:28	22	Q.	Okay. So they got it from the professor	08:31
23	Q.	-- isn't actually -- the brand name is	08:28	23		and chose to go get it or not?	08:31
24		approved for marketing; correct?	08:28	24	A.	Correct.	08:31
25	A.	Correct.	08:28	25	Q.	Other than -- well, did you bring any of	08:31

Page 15			Page 17				
1	Q.	Even the generic drug must go through a	08:28	1		the materials that you used in yesterday's	08:31
2		drug development process and must be submitted to	08:28	2		presentation with you?	08:31
3		the FDA before it can be marketed using an ANDA	08:28	3	A.	No.	08:31
4		rather than an NDA; correct?	08:28	4	Q.	During the presentation during this	08:31
5	A.	Correct.	08:28	5		hour, what -- how much of that was spent on	08:31
6	Q.	So this course that you or this	08:28	6		manufacturing processes, if any?	08:31
7		presentation that you gave yesterday, how long did	08:29	7	A.	Could you explain to me what you mean by	08:31
8		it last?	08:29	8		"manufacturing processes"?	08:31
9	A.	An hour and a half approximately.	08:29	9	Q.	Certainly. The drug development	08:31
10	Q.	How long did you prepare for that	08:29	10		process -- well, let me back that up. Let me	08:32
11		presentation?	08:29	11		start over.	08:32
12	A.	Several hours.	08:29	12		The drug production process involves several	08:32
13	Q.	What did you do to prepare for that	08:29	13		different components. Developing a drug and	08:32
14		presentation?	08:29	14		getting it ready to be manufactured and then	08:32
15	A.	I took my course that I teach routinely	08:29	15		actually going forward and physically producing	08:32
16		at client sites, my book, and a course that I also	08:29	16		the product I will characterize as two separate	08:32
17		teach at conferences routinely, looked at that	08:29	17		components of that process.	08:32
18		core value that was there, based on input from the	08:29	18		Did you discuss during your presentation	08:32
19		professor who invited me, trying to target what	08:30	19		yesterday, that second component, the acts	08:32
20		she thought might be useful for the students to be	08:30	20		associated with physically manufacturing and	08:32
21		exposed in a general sense.	08:30	21		producing a drug product?	08:32
22	Q.	And I -- I understand from your prior	08:30	22	A.	No because the students -- it was an	08:32
23		answer that you distributed some sort of materials	08:30	23		open lecture and the students were allowed to	08:32
24		at that presentation yesterday.	08:30	24		drive it where they wanted to go and many of their	08:33
25	A.	I did via Internet link.	08:30	25		questions were not related to manufacturing.	08:33

5 (Pages 14 to 17)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 18			Page 20		
1	Q. Were you planning to discuss that if	08:33	1	A. The general nature of the consulting	08:36
2	they drove the discussion -- to use your term --	08:33	2	project is to support laboratory and manufacturing	08:36
3	in that direction?	08:33	3	investigation review as a third-party independent.	08:36
4	A. Brief overview, yes.	08:33	4	Q. When did that start?	08:36
5	Q. Do you know the or can you tell us the	08:33	5	A. June last year.	08:36
6	link, the address for the link to the presentation	08:33	6	Q. Of 2010?	08:36
7	materials for yesterday?	08:33	7	A. Yes, sir.	08:36
8	A. Actually, I can't off the top of my	08:33	8	Q. Does that mean that this CV hasn't been	08:36
9	head.	08:33	9	updated since June 2010 or perhaps before then?	08:36
10	Q. Can you tell us generally how one might	08:33	10	A. I don't know. I'd have to go back and	08:36
11	get to that link? Is it available through Delphi,	08:33	11	look and see when it was last updated.	08:36
12	is it available from claycoachonline?	08:33	12	Q. Other than the consulting project and	08:36
13	A. It's available through Delphi in a blind	08:33	13	the presentation you gave yesterday, what -- is	08:36
14	web link.	08:33	14	there anything else that's not on this CV that	08:36
15	Q. What do you mean by blind web link?	08:33	15	relates to your experience or your education?	08:36
16	A. The students and the instructor is the	08:33	16	A. Without going through it line by line, I	08:36
17	only ones that have it.	08:33	17	do not see my assistant -- excuse me associate	08:37
18	Q. So they need some sort of password or	08:33	18	professorship at St. Leo University.	08:37
19	invitation?	08:33	19	Q. Is that a current position?	08:37
20	A. Just the right link to get to the page.	08:33	20	A. It is.	08:37
21	Q. I mean it's not available to anybody who	08:33	21	Q. When did it start?	08:37
22	happens to go to the Delphi website?	08:33	22	A. Sometime I want to say approximately	08:37
23	A. No, sir.	08:33	23	late spring, early summer of last year.	08:37
24	Q. When we get a break sometime today, will	08:34	24	Q. That's St. Leo University?	08:37
25	you see what you can do about figuring out how to	08:34	25	A. Yes, sir.	08:38
Page 19			Page 21		
1	provide me and defense counsel with access to that	08:34	1	Q. And it's associate professor?	08:38
2	link, please?	08:34	2	A. Yes.	08:38
3	A. Sure.	08:34	3	Q. What general --	08:38
4	Q. Thank you.	08:34	4	A. Non-tenured track.	08:38
5	A. Uh-huh.	08:34	5	Q. Okay. Describe that generally. What do	08:38
6	Q. Now other than -- I'll let you make your	08:34	6	you do, what are your responsibilities as an	08:38
7	note.	08:34	7	associate, non-tenured professor at St. Leo	08:38
8	Other than this presentation that you gave	08:34	8	University?	08:38
9	yesterday, is the document that is in front of you	08:34	9	A. I was one of the distance learning	08:38
10	and that is marked as Exhibit 93 current with	08:34	10	instructors.	08:38
11	respect to your education and experience?	08:34	11	Q. What is distance learning?	08:38
12	A. No.	08:35	12	A. Online education.	08:38
13	Q. What else is not on that version of your	08:35	13	Q. So what is your role and what are your	08:38
14	CV that relates to your education and experience?	08:35	14	responsibilities? What do you do?	08:38
15	A. I am on a major consulting project right	08:35	15	A. I oversaw and taught via Internet	08:38
16	now, and that's not on the list.	08:35	16	learning packages provided by the university,	08:38
17	Q. Okay. What's that consulting project?	08:35	17	introductory to science class.	08:38
18	A. I'm not at liberty to share that with	08:35	18	Q. Any direct interaction with students in	08:38
19	you because I'm under a confidentiality agreement.	08:35	19	that role?	08:38
20	Q. Well, is it going to go on your CV at	08:35	20	A. How would you define "direct"?	08:38
21	some point?	08:35	21	Q. Well, did you deal with students	08:38
22	A. Perhaps.	08:35	22	face-to-face or in a classroom setting?	08:38
23	Q. What is the -- without revealing the	08:35	23	A. No.	08:38
24	client, what is the nature generally of that	08:35	24	Q. Did you deal with them exclusively via	08:38
25	consulting project?	08:36	25	online contact?	08:38

6 (Pages 18 to 21)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 22			Page 24		
1	A. No.	08:38	1	right?	08:41
2	Q. How did you interact with your students?	08:38	2	A. That is correct.	08:41
3	A. Online in the course, e-mail and	08:38	3	Q. Analytical methods describe -- am I	08:41
4	telephone.	08:39	4	correct that that generally means the method by	08:41
5	Q. And telephone.	08:39	5	which laboratory testing is conducted on some	08:41
6	You used or you spoke in the past tense when	08:39	6	material that is part of the pharmaceutical --	08:41
7	you described that position. Is it ongoing?	08:39	7	part of a pharmaceutical manufacturing process?	08:41
8	A. I am -- do have that position within the	08:39	8	A. Can you restate that, please?	08:41
9	organization. I'm not currently teaching a course	08:39	9	Q. Sure. When you use the term "analytical	08:41
10	because of additional workload.	08:39	10	method," am I correct in my understanding that	08:41
11	Q. Is it your expectation that you will	08:39	11	that means or is used generally to describe the	08:41
12	teach it again in the future?	08:39	12	method by which laboratory testing is conducted on	08:41
13	A. Yes.	08:39	13	something, some entity that is part of a	08:41
14	Q. Do you believe that the university	08:39	14	pharmaceutical manufacturing process -- whether	08:42
15	shares that expectation?	08:39	15	it's finished product or in-process material or	08:42
16	A. I couldn't say.	08:39	16	raw material or --	08:42
17	Q. Are you being paid by St. Leo University	08:39	17	A. Packaging material.	08:42
18	for -- in any way at the moment?	08:39	18	Q. Okay. So analytical method is	08:42
19	A. At the current moment?	08:39	19	developing a testing method; correct?	08:42
20	Q. Yes.	08:39	20	A. I'd say that's accurate.	08:42
21	A. No.	08:39	21	Q. So your role with Zeneca was entirely in	08:42
22	Q. When did you stop receiving compensation	08:39	22	the laboratory; correct?	08:42
23	from St. Leo University?	08:39	23	A. When you say "entirely in the	08:42
24	A. When the semester ended.	08:39	24	laboratory," could you define that, please?	08:42
25	Q. Last spring?	08:39	25	Q. Well did you do any -- you didn't do	08:42
Page 23			Page 25		
1	A. Whenever it was. I'd have to go back	08:39	1	anything it looks like other than perform job	08:42
2	and look at that.	08:39	2	functions related to and around developing,	08:42
3	Q. Well, there's two semesters in an	08:39	3	validating analytical methods; is that accurate?	08:42
4	academic year.	08:39	4	A. I don't think that's an accurate	08:42
5	A. There are several actually, depends,	08:40	5	statement, no.	08:42
6	distant learning, stuff like that. I would have	08:40	6	Q. Well what else did you do other than	08:42
7	to go back and look it up.	08:40	7	work with developing and validating analytical	08:42
8	Q. Give me your best estimate on when that	08:40	8	methods as your CV says?	08:42
9	semester commenced and ended.	08:40	9	A. As it says here, worked closely with	08:43
10	A. I really can't tell you when it	08:40	10	formulation specialists, designed testing	08:43
11	started. When it ended it was I think somewhere	08:40	11	protocols and methods for new dosage forms.	08:43
12	in June.	08:40	12	Q. Okay. And that is a -- does that have	08:43
13	Q. Of 2010?	08:40	13	anything to do with product manufacturing, the	08:43
14	A. Yes.	08:40	14	actual physical manufacturing process?	08:43
15	Q. Okay. Now, as I look at your CV, I want	08:40	15	A. It does.	08:43
16	to go through that a little bit with you. I see	08:40	16	Q. How?	08:43
17	that your first work experience after you left the	08:40	17	A. There is actually quite of bit of	08:43
18	University of Vermont, graduated from the	08:40	18	extensive formulation development and interaction	08:43
19	University of Vermont is with Zeneca; is that	08:40	19	with the formulators in the initial dosage form	08:43
20	right?	08:41	20	manufacturing.	08:43
21	A. Yes.	08:41	21	Q. Well, what does that have --	08:43
22	Q. As an analytical research chemist?	08:41	22	A. Report it back.	08:43
23	A. That is correct.	08:41	23	Q. What does that have to do with tablet or	08:43
24	Q. And according to your CV, in that role	08:41	24	product manufacturing?	08:43
25	you developed and validated analytical methods;	08:41	25	A. This lays all the basis because this is	08:43

7 (Pages 22 to 25)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 26			Page 28		
1	the initial work that's done to get to the final	08:43	1	Q. Well -- I'm sorry. Go ahead.	08:46
2	validated process in product.	08:43	2	A. And once the method is developed to a	08:46
3	Q. Well, but you're not -- I mean	08:43	3	point where it appears to be validatable, a	08:46
4	Dr. Bliesner your resume says "developing	08:43	4	validation program protocol is developed and then	08:46
5	analytical methods," not validating manufacturing	08:43	5	validated to prove in fact the method works for	08:46
6	processes.	08:43	6	its intended use.	08:46
7	A. As part of that process you are	08:43	7	Q. And according to resume, your primary	08:46
8	interacting very closely with the formulators and	08:43	8	emphasis was on HPLC method development; is that	08:46
9	the manufacturing folks to test their products and	08:44	9	right?	08:46
10	be involved in those cross-functional meetings to	08:44	10	A. That's correct.	08:46
11	make sure that they're hitting what they're	08:44	11	Q. And HPLC stands for high performance	08:46
12	supposed to be hitting and when they have problems	08:44	12	liquid chromatography; am I correct about that?	08:46
13	that, you know -- when they're developing	08:44	13	A. Yes, and it also stands for high	08:46
14	processes, that you are there to provide	08:44	14	pressure liquid chromatography. It's a term that	08:46
15	additional input and feedback with respect to how	08:44	15	is cross-confused sometimes. It's now becoming	08:46
16	your analyses are reflecting on what they're	08:44	16	more popular again.	08:46
17	doing.	08:44	17	Q. On your resume --	08:46
18	Q. What type of products did Zeneca make	08:44	18	A. Yes.	08:46
19	while you were in that job? Solid oral dose,	08:44	19	Q. -- what does it mean?	08:46
20	liquids, gels?	08:44	20	A. High performance liquid chromatography.	08:47
21	A. As a company at large?	08:44	21	Q. And that's a method by which a chemical	08:47
22	Q. Yeah.	08:44	22	analysis is performed on some entity; correct?	08:47
23	A. Specifically I couldn't -- I'd have to	08:44	23	A. How would you define "chemical	08:47
24	go back and look, but it covered the broad lanes	08:44	24	analysis"?	08:47
25	of product types and formulations.	08:44	25	Q. Well, let me --	08:47
Page 27			Page 29		
1	Q. And do you believe it included solid	08:44	1	A. Uh-huh.	08:47
2	oral dose?	08:44	2	Q. -- ask you, Dr. Bliesner. What is high	08:47
3	A. That, it did.	08:44	3	performance liquid chromatography?	08:47
4	Q. Okay. So they were -- were you involved	08:44	4	A. It's a separation technique.	08:47
5	in developing and validating analytical methods	08:44	5	Q. Separation of what?	08:47
6	for tablets?	08:44	6	A. Components and mixtures.	08:47
7	A. Yes, sir.	08:44	7	Q. So it is a technique to analyze	08:47
8	Q. For Digoxin tablets?	08:44	8	components and mixtures of various drug entities;	08:47
9	A. No, sir.	08:44	9	correct?	08:47
10	Q. Have you ever been involved with any	08:45	10	A. Drug products and also to look for	08:47
11	sort of method development or validation with	08:45	11	impurities if you will in actives and drug	08:47
12	respect to Digoxin in any form?	08:45	12	products.	08:47
13	A. No, sir.	08:45	13	Q. All right. So it's a lab-based	08:47
14	Q. Your next job with UDL, you described it	08:45	14	function, am I correct?	08:47
15	as a principal chemist. And again you indicate --	08:45	15	A. That's correct.	08:47
16	hold on one moment. My apologies, Dr. Bliesner,	08:45	16	Q. Your next -- the next work experience on	08:47
17	for the interruption.	08:45	17	your resume is again for UDL and you're listed as	08:48
18	A. It's okay.	08:45	18	analytical group leader. Do you see that on page	08:48
19	Q. You indicate that you are responsible	08:45	19	3?	08:48
20	for developing and validating analytical methods.	08:45	20	A. I do.	08:48
21	Tell me what that means.	08:45	21	Q. And in that role, you indicate you are	08:48
22	A. As we just talked about being part of a	08:45	22	responsible for supervising research chemists.	08:48
23	cross-functional team that supports product	08:45	23	A. Yes.	08:48
24	development to determine the best analytical	08:46	24	Q. Do you see that?	08:48
25	technique to support the required testing and --	08:46	25	Tell me what you did there.	08:48

8 (Pages 26 to 29)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 30			Page 32		
1	A. I was responsible for the people who	08:48	1	back to Zeneca.	08:50
2	were doing method development and validation and	08:48	2	A. Okay.	08:50
3	testing.	08:48	3	Q. As an analytical research chemist, any	08:50
4	Q. Again, a lab-based function?	08:48	4	QA responsibilities?	08:51
5	A. Yes, and we also interacted with product	08:48	5	A. No, QA is a separate function.	08:51
6	development teams and manufacturing.	08:48	6	Q. Okay.	08:51
7	Q. Okay. But your primary responsibilities	08:48	7	A. Distinct and clear separate function or	08:51
8	were in the lab overseeing research chemists who	08:48	8	should be.	08:51
9	were doing the -- performing the tasks you just	08:48	9	Q. And I understand that.	08:51
10	described; correct?	08:48	10	A. Uh-huh.	08:51
11	A. The primary function, yes.	08:48	11	Q. But I need to -- I hope you understand,	08:51
12	Q. The next position you have listed here	08:48	12	Dr. Bliesner, I need to establish certain things	08:51
13	is analytical laboratory manager.	08:49	13	for the record.	08:51
14	A. Yes.	08:49	14	A. Absolutely.	08:51
15	Q. You indicate in that role you supervised	08:49	15	Q. So with Zeneca -- because as you said QA	08:51
16	day-to-day operation of lab -- analytical lab	08:49	16	is a separate and distinct function from the lab	08:51
17	personnel in various tasks that you list there.	08:49	17	operations --	08:51
18	Do you see that?	08:49	18	A. Uh-huh.	08:51
19	A. Including methods validation, routine	08:49	19	Q. -- which are typically referred to as	08:51
20	analysis, equipment qualification and calibration,	08:49	20	quality control; correct?	08:51
21	stability and experimental protocol, yes.	08:49	21	A. No.	08:51
22	Q. Right. And again that's a lab-based	08:49	22	Q. Well --	08:51
23	position.	08:49	23	A. Quality control and quality assurance	08:51
24	A. It is.	08:49	24	are two different functions.	08:51
25	Q. And was while you occupied it.	08:49	25	Q. That's what I meant.	08:51
Page 31			Page 33		
1	A. Yes.	08:49	1	A. Yes.	08:51
2	Q. The next one, Somerset Pharmaceuticals,	08:49	2	Q. Maybe I didn't say that very clearly.	08:51
3	director of analytical research and	08:49	3	A. Uh-huh.	08:51
4	development/quality control. You characterize it	08:49	4	Q. Lab functions are typically within the	08:51
5	as a senior analytical laboratory supervisor.	08:49	5	industry referred to as quality control; is that	08:51
6	Is that also a lab-based position?	08:49	6	correct?	08:51
7	A. It is, in addition to interacting	08:49	7	A. That's a fair statement.	08:51
8	extensively with product development people who --	08:50	8	Q. Okay. And quality assurance -- or QA as	08:51
9	some of whom reported to me, clinical trial	08:50	9	I've been using that term and as I believe you	08:51
10	material manufacturing, dosage formula	08:50	10	understood when I used that term --	08:51
11	manufacturing, some of who reported to me.	08:50	11	A. Uh-huh.	08:51
12	Various different -- it was a small company and	08:50	12	Q. -- is as you described a separate and	08:51
13	everybody wore a lot of hats. In this particular	08:50	13	distinct function totally separate from lab	08:51
14	case we did the whole development bailiwick.	08:50	14	testing and quality control; correct?	08:51
15	Q. Okay. But your position was so you	08:50	15	A. As an oversight function. Quality	08:52
16	interacted with the product development people.	08:50	16	assurance itself is integrated into everything,	08:52
17	A. Some of who reported to me too.	08:50	17	including the lab functions you know, review the	08:52
18	Q. Okay. Those are also lab-based	08:50	18	data, integrity of data, method development	08:52
19	positions; correct?	08:50	19	validation. As far as the title as an oversight,	08:52
20	A. Not all of them, no.	08:50	20	as a final signoff and a separate pair of eyes	08:52
21	Q. What people -- well, did you have any QA	08:50	21	with a different reporting structure, that is the	08:52
22	responsibilities?	08:50	22	QA function.	08:52
23	A. No. QA was a separate function outside	08:50	23	Q. Okay. At Zeneca --	08:52
24	the lab.	08:50	24	A. Uh-huh.	08:52
25	Q. And I guess I should go back. Let's go	08:50	25	Q. -- you had no QA responsibilities;	08:52

9 (Pages 30 to 33)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 34			Page 36		
1	correct?	08:52	1	Q. Okay. And do I understand then that	08:54
2	A. No, but GMP responsibilities that are	08:52	2	when you took this position with Restek, you	08:54
3	oversight by QA.	08:52	3	stepped outside the laboratory and the technical	08:54
4	Q. Dr. Bliesner.	08:52	4	aspect of the pharmaceutical business and	08:55
5	A. Yes.	08:52	5	transitioned to a more business and marketing	08:55
6	Q. This is what I'm talking about. I asked	08:52	6	role?	08:55
7	you very succinctly whether you had QA	08:52	7	A. I don't think that's an accurate	08:55
8	responsibilities. If you would answer that	08:52	8	assessment.	08:55
9	question and only that question, I would	08:52	9	Q. Well, why is it not accurate?	08:55
10	appreciate it; okay?	08:52	10	A. Because the technical aspects all came	08:55
11	Did you have QA responsibilities?	08:52	11	with it in addition to business still.	08:55
12	A. As we define QA -- you and I understand	08:52	12	Q. I understand. But your title is product	08:55
13	-- quality assurance, separate function,	08:52	13	marketing manager. And as you described your	08:55
14	oversight, no.	08:52	14	responsibilities, you were hired to and did assist	08:55
15	Q. Same question with respect to the next	08:52	15	them with trying to increase sales of HPLC	08:55
16	position you have listed, UDL Laboratories and	08:52	16	columns; right?	08:55
17	principal chemist. Did you have any QA	08:52	17	A. I did for a brief period of time.	08:55
18	responsibilities?	08:52	18	Q. And your -- what do you mean by a brief	08:55
19	A. As we've defined it, no.	08:53	19	period of time? Does that mean you were only	08:55
20	Q. Same question with respect to the next	08:53	20	there for five months, is that what you mean?	08:55
21	UDL position you have as analytical group leader	08:53	21	A. I only served in that position for five	08:55
22	on your CV. As we've defined QA responsibilities,	08:53	22	months.	08:55
23	did you have any of those QA responsibilities in	08:53	23	Q. And then you transitioned to director of	08:55
24	that position?	08:53	24	Restek analytical services?	08:55
25	A. No.	08:53	25	A. I created the position and the title.	08:55
Page 35			Page 37		
1	Q. As an analytical laboratory manager for	08:53	1	Q. Okay. And backing up to your product	08:55
2	Somerset Pharmaceuticals, did you have any QA	08:53	2	marketing manager position.	08:56
3	responsibilities?	08:53	3	A. Uh-huh.	08:56
4	A. In the formal sense, as QA as we've	08:53	4	Q. Did you have any QA responsibilities in	08:56
5	defined it, no.	08:53	5	that role?	08:56
6	Q. As the director of analytical research	08:53	6	A. Yes.	08:56
7	and development/quality control for Somerset	08:53	7	Q. Really?	08:56
8	Pharmaceuticals, any QA responsibilities?	08:53	8	A. For HPLC column manufacturing.	08:56
9	A. No.	08:53	9	Q. You had actual oversight responsibility	08:56
10	Q. Moving to the next entry in your CV,	08:53	10	for checking the compliance of product	08:56
11	HPLC, product marketing manager for Restek	08:54	11	manufacturing with specifications?	08:56
12	Corporation apparently at Penn State University.	08:54	12	A. For HPLC columns.	08:56
13	Tell me about that position.	08:54	13	Q. What do you mean by that? Tell me what	08:56
14	A. It was not at Penn State. It's a state	08:54	14	distinction you're making.	08:56
15	college.	08:54	15	A. HPLC column is a major component of high	08:56
16	Q. Is that different?	08:54	16	performance liquid chromatography.	08:56
17	A. Yes.	08:54	17	Q. I understand.	08:56
18	Q. Is that not Penn State?	08:54	18	A. We manufactured HPLC columns at Restek.	08:56
19	A. Yes.	08:54	19	Q. Did Restek manufacture any drug	08:56
20	Q. My apologies.	08:54	20	products?	08:56
21	Tell me about that position. What did you do?	08:54	21	A. No.	08:56
22	A. Initially, I stepped into a business	08:54	22	Q. So as director of analytical services,	08:56
23	role, business development role, to assist them in	08:54	23	that position has -- again is not associated with	08:56
24	finding ways to increase their sales of HPLC	08:54	24	manufacturing drug products, am I correct?	08:57
25	products.	08:54	25	A. We did not manufacture products on site.	08:57

10 (Pages 34 to 37)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 38			Page 40		
1	Q. Did you have any role or responsibility	08:57	1	A. Some of them, yes.	08:59
2	for manufacturing -- for any aspect of	08:57	2	Q. What do you mean by some of them?	08:59
3	manufacturing any drug product when you were	08:57	3	A. I interacted primarily with the client	08:59
4	employed by Restek?	08:57	4	as the first line.	08:59
5	A. I can't say for sure because we	08:57	5	Q. You mean you were the first line -- you	09:00
6	consulted to the industry as well and we may have	08:57	6	were Restek's front line person interacting with	09:00
7	performed some consultation with respect to drug	08:57	7	the client. Is that what you mean by that?	09:00
8	product manufacturers.	08:57	8	A. Yes, sir. For this division, Restek	09:00
9	Q. Dr. Bliesner, I asked what your	08:57	9	Analytical Services.	09:00
10	experience was, not the company as a whole.	08:57	10	Q. Well, your job duties and	09:00
11	A. No, no. I would have been the one that	08:57	11	responsibilities as you described them included	09:00
12	would have been providing that consulting to the	08:57	12	market research, drafting a business plan, and	09:00
13	manufacturing of drug product. I don't recall	08:57	13	obtaining funding and approval from Restek.	09:00
14	whether we did or not, but we did provide	08:58	14	You go on to describe what Restek does, but	09:00
15	consultation in addition to the lab services as	08:58	15	you don't say anything about your -- about you	09:00
16	well. So I can't say definitively that I did or	08:58	16	being involved in any of the analytical method	09:00
17	did not have input into the drug manufacturing	08:58	17	development consultation, do you?	09:00
18	process.	08:58	18	A. If I was to list this here, the document	09:00
19	Q. What consultation did you yourself	08:58	19	would be about 25 pages long for all the different	09:00
20	provide while you were employed by Restek to -- to	08:58	20	jobs that I've had.	09:00
21	drug product manufacturers?	08:58	21	Q. Dr. Bliesner, I'm merely pointing out	09:00
22	A. We were in constant contact with them	08:58	22	that you described your job duties and	09:00
23	because they were our customers for the columns	08:58	23	responsibilities strictly in a business capacity;	09:00
24	and the lab services. So we provided consultation	08:58	24	is that right?	09:00
25	on many aspects of the drug development process,	08:58	25	A. No, that's not correct.	09:00
Page 39			Page 41		
1	production, manufacturing.	08:58	1	Q. Your statement on here says that you	09:01
2	Q. Are you telling me that you were	08:58	2	were responsible for conception, design, building,	09:01
3	involved with developing drug products for other	08:58	3	staffing, and qualification of Restek Analytical	09:01
4	companies while you were employed by Restek?	08:58	4	Services.	09:01
5	A. They were our clients. We consulted	08:58	5	A. That is correct.	09:01
6	with them if they needed things.	08:58	6	Q. And you go on to say that included	09:01
7	Q. You consulted with them with respect to	08:58	7	conducting market research, drafting a business	09:01
8	various functionality issues of your HPLC columns;	08:58	8	plan, and obtaining funding.	09:01
9	correct?	08:58	9	A. That is correct.	09:01
10	A. No, not necessarily. We did contract	08:58	10	Q. You don't say anything about interacting	09:01
11	work, analytical work and product development work	08:58	11	with clients on assisting with development of	09:01
12	for them as part of the mission.	08:58	12	analytical methods.	09:01
13	Q. Well, as part of the mission, as I read	08:58	13	A. As I said, if I put everything down I	09:01
14	your CV, Dr. Bliesner, that you prepared, it lists	08:59	14	did here, the document would be 25 pages long.	09:01
15	only business functions. It doesn't say anything	08:59	15	This is a summary resume to send out to people.	09:01
16	about being involved in drug development	08:59	16	Could I interrupt for a second, please?	09:01
17	processes, does it?	08:59	17	Q. Would you like to take a break?	09:01
18	A. If you look at the director of Restek	08:59	18	A. Yes, please.	09:01
19	Analytical Services, it offers analytical method	08:59	19	MR. ANDERTON: Absolutely.	09:01
20	development, validation, HPLC, GC, education,	08:59	20	THE VIDEOGRAPHER: The time is 9:01 a.m.	09:01
21	training, customer stationary phase design, CGMP	08:59	21	We're going off the record briefly.	09:01
22	regulatory services and support. That's where	08:59	22	(Short break)	09:12
23	that would fall into.	08:59	23	THE VIDEOGRAPHER: The time is 9:12 a.m.	09:12
24	Q. And your testimony is that you performed	08:59	24	We're back on the record. This is the	09:13
25	those functions while you were at Restek?	08:59	25	beginning of tape two.	09:13

11 (Pages 38 to 41)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

<p style="text-align: right;">Page 42</p> <p>1 BY MR. ANDERTON: 09:13</p> <p>2 Q. Dr. Bliesner, -- hey Mike. Mike? 09:13</p> <p>3 MR. KERENSKY: Yes. 09:13</p> <p>4 MR. ANDERTON: If you're going to be 09:13</p> <p>5 typing -- 09:13</p> <p>6 MR. KERENSKY: All right. I'll put it 09:13</p> <p>7 back on mute. Happens all the time. I'm 09:13</p> <p>8 sorry. 09:13</p> <p>9 MR. ANDERTON: That's all right. 09:13</p> <p>10 BY MR. ANDERTON: 09:13</p> <p>11 Q. All right. Dr. Bliesner, we were 09:13</p> <p>12 discussing various things on your resume and we 09:13</p> <p>13 left off -- or your CV. We left off with director 09:13</p> <p>14 of analytical services for Restek. 09:13</p> <p>15 A. Restek, yes. 09:13</p> <p>16 Q. Restek. Sorry. And the State College 09:13</p> <p>17 of Pennsylvania. The next -- well, let me let me 09:13</p> <p>18 ask one final question about that position. 09:13</p> <p>19 The consultation that you described being 09:14</p> <p>20 involved with in that position was primarily 09:14</p> <p>21 consultation -- well, was exclusively consultation 09:14</p> <p>22 related to lab-based activities; correct? 09:14</p> <p>23 A. No, I don't think you'd say that 09:14</p> <p>24 exclusively. We went into a lot of different 09:14</p> <p>25 client sites, interacted with groups of folks at 09:14</p>	<p style="text-align: right;">Page 44</p> <p>1 services because there was formulation development 09:15</p> <p>2 discussions that went on in there as well. 09:15</p> <p>3 Q. When you left Restek and went to work -- 09:15</p> <p>4 the next position listed on your CV is 09:15</p> <p>5 vice-president of operations for Laboratory 09:15</p> <p>6 Management Systems in New Castle, Delaware. 09:15</p> <p>7 A. That's correct. 09:15</p> <p>8 Q. According to your CV, you created and 09:16</p> <p>9 drove sales and marketing plans; is that right? 09:16</p> <p>10 A. As one part of my responsibilities, yes. 09:16</p> <p>11 Q. What else did you do? 09:16</p> <p>12 A. Primary responsibility took up the 09:16</p> <p>13 lion's share of the time as I was an active 09:16</p> <p>14 consultant with the Wyeth and Schering Plough 09:16</p> <p>15 consent decrees. 09:16</p> <p>16 Q. Doing what? 09:16</p> <p>17 A. Being part of the FDA-mandated 09:16</p> <p>18 third-party expert contingent consult, where we 09:16</p> <p>19 went in and did very detailed, thorough 09:16</p> <p>20 assessments, documented the findings, developed 09:16</p> <p>21 corrective actions and went back in and did 09:16</p> <p>22 verification and then backed the actions that had 09:16</p> <p>23 been put into place that were stable -- were 09:16</p> <p>24 verifiable and sustainable from a quality systems 09:16</p> <p>25 standpoint. 09:16</p>
<p style="text-align: right;">Page 43</p> <p>1 the client sites which included, you know, product 09:14</p> <p>2 development, manufacturing types, lab types, 09:14</p> <p>3 usually looking for a source of additional 09:14</p> <p>4 information in addition to solving problems. 09:14</p> <p>5 Q. Primarily lab-based activities that you 09:14</p> <p>6 were giving consultation on? 09:14</p> <p>7 A. I wouldn't say primarily. 09:14</p> <p>8 Q. Well, you sold -- 09:14</p> <p>9 A. It was very broad-based in our approach 09:14</p> <p>10 in how we were trying to line up customers. 09:14</p> <p>11 Q. Well, you sold HPLC columns; right? 09:14</p> <p>12 A. And services. 09:15</p> <p>13 Q. And what type of services? What do you 09:15</p> <p>14 mean by services? 09:15</p> <p>15 A. That's what Restek Analytical Services 09:15</p> <p>16 was all about. It wasn't just about selling HPLC 09:15</p> <p>17 columns. It was about selling contract analytical 09:15</p> <p>18 services and providing consulting services -- GMP 09:15</p> <p>19 training, those types of things -- to the industry 09:15</p> <p>20 so they could partner with us and be interested in 09:15</p> <p>21 buying the columns and we would validate the 09:15</p> <p>22 methods. 09:15</p> <p>23 Q. Analytical services again relates to lab 09:15</p> <p>24 functions; right? 09:15</p> <p>25 A. It wasn't necessarily all analytical 09:15</p>	<p style="text-align: right;">Page 45</p> <p>1 Q. Wyeth and who else? 09:16</p> <p>2 A. Schering Plough. 09:16</p> <p>3 Q. Schering Plough. Both were under 09:16</p> <p>4 consent decrees? 09:16</p> <p>5 A. They were. 09:17</p> <p>6 Q. Did you visit both of those companies 09:17</p> <p>7 while you were employed by Laboratory Management 09:17</p> <p>8 Systems? 09:17</p> <p>9 A. When you say "visit," they're very large 09:17</p> <p>10 organizations that have many different sites. 09:17</p> <p>11 Q. Did you visit any of them? 09:17</p> <p>12 A. Yes, sir. 09:17</p> <p>13 Q. For both companies? 09:17</p> <p>14 A. Yes, sir. 09:17</p> <p>15 Q. And -- 09:17</p> <p>16 A. The visit actually was on site 09:17</p> <p>17 extensively for some of them. 09:17</p> <p>18 Q. And so you were part of what I'll 09:17</p> <p>19 characterize as the remediation activities for 09:17</p> <p>20 both of those companies? 09:17</p> <p>21 A. I wouldn't characterize it as such. 09:17</p> <p>22 Q. What's wrong with my term remediation 09:17</p> <p>23 activities? 09:17</p> <p>24 A. Remediation assumes that you've already 09:17</p> <p>25 found everything that was wrong. 09:17</p>

12 (Pages 42 to 45)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 46			Page 48		
1	Q. Okay. But there were certainly	09:17	1	documented things, how data was collected, and you	09:19
2	remediation activities.	09:17	2	would go soup to nuts, systematic approach,	09:19
3	A. That followed, yes.	09:17	3	looking through to see if they, in fact, had	09:19
4	Q. Well, if you're under a consent decree,	09:17	4	quality systems or any systems in place, whether	09:20
5	there are certain things that have already been	09:17	5	they had procedures in place, whether people were	09:20
6	identified; right?	09:17	6	trained and just in a laboratory notebook document	09:20
7	A. The FDA would have found and documented	09:17	7	all these findings and go back and write them up	09:20
8	through 483s, warning letters, and presented an	09:17	8	as findings from the assessment, very similar to	09:20
9	EIR, continuing deficiencies, yes.	09:18	9	what the FDA would do on a 483. A very extensive,	09:20
10	Q. And tell me about the process that	09:18	10	heavy-duty process.	09:20
11	you -- and let's ask first about Wyeth.	09:18	11	That was only the first part.	09:20
12	A. Uh-huh.	09:18	12	Q. What was the second part?	09:20
13	Q. Tell me about the process that you	09:18	13	A. The second part was a compilation of all	09:20
14	followed as you provided consulting services to	09:18	14	of the findings into a report.	09:20
15	them to help them address the issues that were	09:18	15	Q. The findings meaning your analysis of	09:20
16	raised by the consent decree and the underlying	09:18	16	the data as you described it and protocols that	09:20
17	regulatory activities that resulted in that	09:18	17	you reviewed and all the other information that	09:20
18	consent decree.	09:18	18	you reviewed.	09:20
19	A. Okay.	09:18	19	A. Systems in general; okay? Quality	09:20
20	Q. What process did you follow?	09:18	20	system, laboratory control system, product system,	09:20
21	A. As a global?	09:18	21	packaging, labeling, all of those different	09:20
22	Q. Yeah, generally.	09:18	22	things. You know, it was a detailed assessment	09:20
23	A. Generally.	09:18	23	and that would include reviewing training records	09:20
24	Q. And then I'll ask more specific	09:18	24	for instance for the individuals that are there,	09:20
25	questions based on your response.	09:18	25	looking at, you know, production records.	09:20
Page 47			Page 49		
1	A. First of all, each consent decree as I'm	09:18	1	Everything you would imagine that constitutes a	09:21
2	sure you know is an individually negotiated plan.	09:18	2	modern pharmaceutical manufacturing system -- down	09:21
3	Q. Understood.	09:18	3	to excruciating details.	09:21
4	A. In the Wyeth consent decree, we first	09:18	4	Q. That was all part of your consulting?	09:21
5	came in and did very detailed assessments of the	09:18	5	A. Yes. We had a 150 people team initially	09:21
6	major quality system elements.	09:18	6	on the one site with Wyeth.	09:21
7	Q. Which involved what?	09:18	7	Q. How long did that process take?	09:21
8	A. Going into individual departments --	09:19	8	A. The initial assessment?	09:21
9	laboratories, manufacturing areas, packaging	09:19	9	Q. Yes.	09:21
10	areas -- usually in teams of two people and asking	09:19	10	A. The initial site where we started --	09:21
11	questions, performing interviews, looking at data,	09:19	11	it's been a long time. The assessment ran	09:21
12	looking at protocols, the whole plethora of	09:19	12	somewhere in the neighborhood of approximately	09:21
13	activities for each one of the quality system	09:19	13	three months.	09:21
14	elements. Document them.	09:19	14	Q. With 150 people on site for three	09:21
15	Q. Looking at data and looking at	09:19	15	months?	09:21
16	protocols, two things that you identified in that	09:19	16	A. Absolutely.	09:21
17	response. What do each of those mean? Looking at	09:19	17	Q. 150 laboratory management systems	09:21
18	what type of data, looking at what type of	09:19	18	employees on Wyeth's site for three months?	09:21
19	protocols?	09:19	19	A. We were subcontractors as part of a	09:21
20	A. It really depended because it was a huge	09:19	20	team.	09:22
21	organization and addressed many different	09:19	21	Q. Okay. As you performed that	09:22
22	components. So you would be assigned a department	09:19	22	assessment.	09:22
23	for instance that you could go in on for a	09:19	23	A. Uh-huh.	09:22
24	particular week and you would determine their work	09:19	24	Q. That's a correct term?	09:22
25	flow, how they conducted business, how they	09:19	25	A. Yes.	09:22

13 (Pages 46 to 49)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 50			Page 52		
1	Q. Is that the same thing as an audit?	09:22	1	come in the form of a corporate entity, quality	09:24
2	A. I don't think I would define it like	09:22	2	assurance coming down to a specific site and	09:24
3	that, but...	09:22	3	performing a compliance assessment that's an audit	09:24
4	Q. Well --	09:22	4	to try to determine stuff.	09:24
5	A. It's the same process, yeah.	09:22	5	When corporate comes down to a site, it isn't	09:24
6	Q. Okay. So if I describe the process that	09:22	6	necessarily a free and open sharing of things with	09:24
7	you just described.	09:22	7	individuals because it's corporate. So that is	09:24
8	A. Uh-huh.	09:22	8	how audits work per se.	09:24
9	Q. 150 people on site for three months,	09:22	9	An assessment is when -- I've actually just	09:24
10	soup to nuts, virtually everything you can think	09:22	10	recently finished a very extensive one where we	09:24
11	of with respect to a manufacturing and production	09:22	11	would sit down and it's full, open, and honest	09:24
12	process.	09:22	12	disclosure, everybody is laying things out because	09:24
13	A. Uh-huh.	09:22	13	you really want to get to the root cause during an	09:24
14	Q. That's an accurate description of what	09:22	14	assessment, self-assessment, to find out what's	09:25
15	you guys -- the activity you undertook.	09:22	15	broken and what potential corrective actions may	09:25
16	A. Everything. All of the components of	09:22	16	be and how to implement corrective and preventive	09:25
17	the quality systems that constituted that.	09:22	17	actions and verify the actions, collecting these	09:25
18	Q. So if I described that process as an	09:22	18	data, all the things we've described.	09:25
19	audit, would that be an accurate or a fair	09:22	19	Q. So then as you understand and use, as	09:25
20	characterization?	09:22	20	you used the term audit, does that mean you don't	09:25
21	A. Perhaps. There's confusion in the	09:23	21	think it's -- that there's as much disclosure and	09:25
22	industry in general about what's an assessment,	09:23	22	openness when an audit is being conducted?	09:25
23	what's a self-assessment, what's an audit, what's	09:23	23	A. I would say that's a fair assessment,	09:25
24	an inspection, so...	09:23	24	yes. Because people volunteer information during	09:25
25	Q. I understand.	09:23	25	an assessment, but if the FDA comes in to do an	09:25
Page 51			Page 53		
1	A. Yes.	09:23	1	audit, people don't volunteer information.	09:25
2	Q. I'm asking you.	09:23	2	Q. Well, if corporate comes in to do an	09:25
3	A. To me, personally?	09:23	3	audit, they volunteer information don't they,	09:25
4	Q. Yes.	09:23	4	typically?	09:25
5	A. An audit is a like the agency coming in	09:23	5	A. It's restrained in my experience.	09:25
6	and doing something from the outside. It's not	09:23	6	Q. Do you feel that the people who are the	09:25
7	necessarily open and collaborative. This	09:23	7	subject of either an assessment or an audit make	09:25
8	assessment was full disclosure from all employees	09:23	8	that type of distinction or do they kind of look	09:25
9	and everything. You know, sit down, tell us	09:23	9	at it as though it's corporate or the FDA or a	09:25
10	what's wrong, tell us everything that's there, you	09:23	10	third party asking questions about what they do	09:26
11	know, everybody volunteering information. I	09:23	11	and how they do it?	09:26
12	consider that to be different than an audit.	09:23	12	A. I don't know if I really understand the	09:26
13	Q. Well, when you -- so you then used the	09:23	13	question.	09:26
14	term audit and believe it is best used only to	09:23	14	MR. ANDERTON: Can you read that back,	09:26
15	apply to a -- a -- I guess I'll characterize that	09:23	15	Phil.	09:26
16	as third-party or just the FDA? I mean I'm not	09:24	16	THE WITNESS: I think there's a couple of	09:26
17	sure I understand the distinction.	09:24	17	questions in there. I think people in	09:26
18	A. And to be perfectly honest with you,	09:24	18	general -- again, confusion on terms. We'll	09:26
19	there's confusion in the industry too. So I don't	09:24	19	use my definition audit, a third party coming	09:26
20	know if your statement is the best description of	09:24	20	in or a corporate entity, something like that,	09:26
21	it.	09:24	21	as opposed to assessment, being	09:26
22	Q. Well, then I mean what is -- what is the	09:24	22	self-assessment you want to uncover	09:26
23	difference between an audit and the assessment	09:24	23	everything. Those two distinctions. I think	09:26
24	that you just described?	09:24	24	people respond to audits and assessments,	09:26
25	A. An audit, in my experience, they usually	09:24	25	self-assessments differently, yes. And the	09:26

14 (Pages 50 to 53)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 54		Page 56	
1	reason for that is that audits -- corporate, 09:26	1	Q. And sometimes you're doing an assessment 09:29
2	FDA or whatever -- obviously carry tremendous 09:27	2	based on an FDA warning letter; correct? 09:29
3	consequences. 09:27	3	A. Or a preparation for a preapproval 09:29
4	BY MR. ANDERTON: 09:27	4	inspection for FDA, another example. 09:29
5	Q. Okay. When you performed this 09:27	5	Q. But to answer my question, it's true 09:29
6	assessment of Wyeth with 150 people on site for 09:27	6	that you've done assessments where a company 09:29
7	three months. 09:27	7	receives a warning letter, they hire you or people 09:29
8	A. About three months. 09:27	8	that you work with and for and they ask you to do 09:29
9	Q. Okay. Fair enough. 09:27	9	what you've described as an assessment on the 09:29
10	A. And there are several other sites that 09:27	10	basis of that warning letter; is that true? 09:29
11	were involved as well. 09:27	11	A. That is correct, yes. 09:29
12	Q. Fair enough. Well, when your team 09:27	12	Q. All right. And have you also done 09:29
13	performed this assessment that lasted 09:27	13	assessments on the basis of FDA 483s? 09:29
14	approximately three months at various locations of 09:27	14	A. Specifically 483s? 09:29
15	Wyeth and you did your soup to nuts review, did 09:27	15	Q. Yeah. 09:29
16	you have access to any information that you 09:27	16	A. No. 09:29
17	wanted? 09:27	17	Q. Okay. When you -- when you do those -- 09:29
18	A. By agreement and communication with the 09:27	18	and I believe last time you testified that you've 09:29
19	company, the official position was yes, we were to 09:27	19	done about five -- and I think the term that you 09:29
20	have access to any information we wished. 09:27	20	used was audit rather than assessment, you've done 09:30
21	Q. And by that you mean that was a 09:27	21	about five GMP compliance audits in your career. 09:30
22	condition of you doing the assessment because it's 09:27	22	Does that sound about right? 09:30
23	necessary to do it properly? 09:27	23	A. Let me think about it for a second. 09:30
24	A. That's correct. 09:28	24	Q. Take your time. 09:30
25	Q. And that's typical when you do that type 09:28	25	A. Yeah, about five or six. 09:30
Page 55		Page 57	
1	of assessment; correct? You need to have full 09:28	1	Q. Back to the assessments that you said 09:31
2	access to whatever documents you think are 09:28	2	you've done for or on the basis of an FDA warning 09:31
3	necessary and appropriate in order to properly 09:28	3	letter. When you undertook those engagements, was 09:31
4	perform an assessment as you've described; is that 09:28	4	it also a condition of your engagement that you 09:31
5	right? 09:28	5	would have access to the documents you and your 09:31
6	A. "Typical" is a very broad term. I don't 09:28	6	team felt were necessary to review in order to 09:31
7	know if I'd necessarily use it. Because, again, 09:28	7	conduct the assessment? 09:31
8	each consent decree as you know is negotiated 09:28	8	A. In the circumstance where it was just a 09:31
9	differently and may involve certain departments 09:28	9	warning letter, the project did not start out as 09:31
10	within the larger company that may or may not 09:28	10	we're bringing you in to do an assessment. It 09:31
11	necessarily be involved with the consent decree or 09:28	11	evolved into that. 09:31
12	initially involved in the consent decree for 09:28	12	Q. And when it did -- 09:31
13	example. 09:28	13	A. Yes. 09:31
14	Q. The consent decree -- 09:28	14	Q. -- did you insist on having full access 09:31
15	A. Yes. 09:28	15	to the documents you deemed necessary to properly 09:32
16	Q. -- or if it's another regulatory 09:28	16	conduct your assessment? 09:32
17	document is a starting point for the assessment; 09:28	17	A. We didn't insist. We just expected 09:32
18	correct? 09:28	18	because it was the next evolution for the client 09:32
19	A. When you say "another regulatory 09:28	19	to ask for it that we would have what we needed. 09:32
20	document." 09:28	20	Q. Would you do an assessment if a 09:32
21	Q. Might be a 483, might be a warning 09:28	21	potential client said no, we're not going to give 09:32
22	letter. You've done consulting engagements where 09:28	22	you access to certain documents? Production 09:32
23	the company wasn't involved in a negotiated 09:29	23	records for example. 09:32
24	consent decree; correct? 09:29	24	A. Would we do the assessment? 09:32
25	A. That's correct. 09:29	25	Q. Yeah. 09:32

15 (Pages 54 to 57)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 58			Page 60		
1	A. Depends on what the client wants out of	09:32	1	A. On the floor in manufacturing?	09:34
2	the assessment.	09:32	2	Q. Yes.	09:34
3	Q. Well, if a client hired you to assess	09:32	3	A. During product development, yes.	09:34
4	GMP compliance.	09:32	4	Q. What did you do?	09:34
5	A. Okay. In general.	09:32	5	A. Helped troubleshoot a fluid bed dryer.	09:34
6	Q. Yes.	09:32	6	Q. Tell me more about that.	09:34
7	A. Uh-huh.	09:32	7	A. I was, had one of my individuals at the	09:34
8	Q. And said I'm not going to -- I want you	09:32	8	Somerset facility. He was working with a Glatt,	09:34
9	to do it without looking at production records,	09:32	9	G-L-A-T-T. It's a fluid bed coater if you will.	09:34
10	would you do that?	09:32	10	And he was having a lot of problems with it and	09:34
11	A. If it was to be a comprehensive review	09:32	11	everything else and asked me if I would come in	09:35
12	of compliance with the GMPs using a quality	09:32	12	and watch him go through the process and if I	09:35
13	systems based approach, we would inform the client	09:32	13	could offer any suggestions on how to correct it.	09:35
14	that unless we had access to those records, that	09:32	14	Q. Okay. Have you ever actually -- other	09:35
15	they wouldn't be getting what they were asking	09:33	15	than a support functionality as, you know, since	09:35
16	for.	09:33	16	it's troubleshooting like that --	09:35
17	Q. So they wouldn't be getting a	09:33	17	A. Uh-huh.	09:35
18	comprehensive, accurate assessment of GMP	09:33	18	Q. -- have you ever actually had daily	09:35
19	compliance?	09:33	19	responsibilities in the manufacturing context?	09:35
20	A. Any my opinion, if they did not give	09:33	20	A. No.	09:35
21	open access to the records, yes.	09:33	21	Q. In a packaging context?	09:35
22	Q. To the production records. That's the	09:33	22	A. As in a production environment package?	09:35
23	records I was talking about.	09:33	23	Q. Yes.	09:35
24	A. Well, specifically -- it depends what	09:33	24	A. No.	09:35
25	the client wants; okay? If the client wants the	09:33	25	Q. In a QA context. Have you ever been	09:35
Page 59			Page 61		
1	whole thing, then access to production records	09:33	1	directly in the QA operation or functionality?	09:35
2	would probably be something you would want to have	09:33	2	A. As we defined it for QA?	09:35
3	access to.	09:33	3	Q. Yes.	09:35
4	Q. And I want -- I guess I want to make	09:33	4	A. Separate oversight?	09:35
5	sure this is clear because I was talking about	09:33	5	Q. Yeah.	09:35
6	production records.	09:33	6	A. No.	09:35
7	A. Okay. I misunderstood you.	09:33	7	Q. Do you have a copy of your report,	09:36
8	Q. I said it -- I thought I said it pretty	09:33	8	Dr. Bliesner?	09:36
9	clearly.	09:33	9	A. I do.	09:36
10	A. Sorry.	09:33	10	Q. All right. Why don't you get it in	09:36
11	Q. If a client hired you to assess its	09:33	11	front of you --	09:36
12	general GMP compliance.	09:33	12	A. Okay.	09:36
13	A. Right.	09:33	13	Q. -- please. And, Mike, this is Exhibit	09:36
14	Q. And said, I don't want to give you -- I,	09:33	14	92. I believe is the version we were looking at	09:36
15	client, don't want to give you access to the	09:33	15	last time.	09:36
16	production records, you can do it from other	09:33	16	A. Now, this is my personal version so I	09:36
17	records, could you properly do that?	09:33	17	don't have a copy of the 92 that you're working	09:36
18	A. If it was a -- included an assessment of	09:33	18	off of.	09:36
19	the production system?	09:33	19	Q. Well, let's make sure, then.	09:36
20	Q. Yes.	09:33	20	A. I know there was a couple of page	09:36
21	A. No, you couldn't.	09:34	21	discrepancies before.	09:36
22	Q. Couldn't do it?	09:34	22	Q. I understand. So we're going to hand	09:36
23	A. In my opinion, no.	09:34	23	you a copy of Exhibit 92.	09:36
24	Q. Okay. In your work experience, have you	09:34	24	A. Okay.	09:36
25	ever worked in manufacturing?	09:34	25	Q. Turn to page -- well, what is my page.	09:36

16 (Pages 58 to 61)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 62			Page 64		
1	A. It's 92. We should be okay now.	09:37	1	referring to when you said "we know."	09:46
2	Q. Okay. Fair enough. Yeah, these should	09:37	2	A. Uh-huh.	09:46
3	be the same actually.	09:37	3	Q. "Product made it to market."	09:46
4	A. Yes.	09:37	4	A. Uh-huh. And you asked me to identify	09:46
5	Q. So.	09:37	5	all those circumstances in the report so that's	09:46
6	A. It was just there was two different	09:37	6	what I'm doing. Would you like me to stop?	09:46
7	exhibits before and they were a page off because	09:37	7	Q. Well, how many do you think there are?	09:46
8	of formatting or something like that.	09:37	8	A. I'm going to finish reviewing the report	09:46
9	Q. Okay.	09:37	9	and then I'll tell you.	09:46
10	A. With respect to my format.	09:37	10	Q. Answer my question. How many do you	09:46
11	Q. So turn to page 21.	09:37	11	think there are?	09:46
12	A. Okay.	09:37	12	A. I'm not going to say off the top of my	09:46
13	Q. And paragraph number 8 on page 21 which	09:37	13	head.	09:46
14	has the heading "conclusions."	09:37	14	Q. Did you -- did you prepare for this	09:46
15	Do you see that?	09:37	15	deposition, Dr. Bliesner?	09:46
16	A. Yes.	09:37	16	A. Today?	09:46
17	Q. And in that paragraph, you issue, I	09:37	17	Q. Yes.	09:46
18	guess, your opinion in this case; is that	09:37	18	MR. KERENSKY: Mike, that's an	09:46
19	accurate?	09:37	19	unnecessary question. You don't have to	09:46
20	A. It is my opinion based on the documents	09:37	20	answer that, Mr. Bliesner.	09:46
21	I reviewed.	09:37	21	MR. ANDERTON: Are you instructing him	09:46
22	Q. Okay. And your opinion is that	09:37	22	not to answer that, Mike?	09:46
23	adulterated drug product made it to the	09:38	23	MR. KERENSKY: He's not because that's an	09:46
24	marketplace.	09:38	24	unprofessional question.	09:46
25	Is that a fair characterization of your	09:38	25	MR. ANDERTON: Are you instructing him	09:46
Page 63			Page 65		
1	opinion?	09:38	1	not to answer?	09:46
2	A. We know it did because the pharmacist	09:38	2	MR. KERENSKY: Yes. What you're doing --	09:46
3	found product that was double-thick.	09:38	3	MR. ANDERTON: On what basis?	09:46
4	Q. Well, when you give that response, are	09:38	4	MR. KERENSKY: Change the question, Mike.	09:46
5	you talking about the 2004 circumstances where a	09:38	5	MR. ANDERTON: On what basis are you	09:47
6	pharmacist reported a double-thick tablet?	09:38	6	instructing him not to answer?	09:47
7	A. I'd have to go back through and take a	09:38	7	MR. KERENSKY: Because it's harassing.	09:47
8	look.	09:38	8	MR. ANDERTON: I'm not harassing him.	09:47
9	Q. Please do.	09:38	9	I'm asking him -- I'm going to get into this	09:47
10	A. Do you have a sticky by chance?	09:40	10	line of questioning whether at this moment or	09:47
11	Q. Yes. I don't but?	09:40	11	some other time. I'm allowed to inquire what	09:47
12	MS. DREWES: I do.	09:40	12	he did to prepare.	09:47
13	THE WITNESS: Can I have?	09:40	13	MR. KERENSKY: All right. Maybe a later	09:47
14	MS. DREWES: Sure.	09:40	14	time when you're actually asking those	09:47
15	THE WITNESS: Bunches of them, please.	09:40	15	questions we'll answer that question.	09:47
16	MS. DREWES: Here.	09:40	16	MR. ANDERTON: No, Mike, you cannot	09:47
17	THE WITNESS: Just to make sure. Else	09:40	17	instruct a witness not to answer because you	09:47
18	you know me, I'll be writing all over this	09:40	18	don't like the timing of the question.	09:47
19	thing.	09:40	19	MR. KERENSKY: Yes, I can.	09:47
20	BY MR. ANDERTON:	09:46	20	MR. ANDERTON: No, you cannot.	09:47
21	Q. Dr. Bliesner, are you re-reading your	09:46	21	MR. KERENSKY: Let him finish answering	09:47
22	report?	09:46	22	the question you've asked.	09:47
23	A. No, I'm just being careful, make sure	09:46	23	MR. ANDERTON: I'm asking a different	09:47
24	that I pull out the information that you wanted.	09:46	24	question now. Dr. Bliesner --	09:47
25	Q. Well, I asked you what you were	09:46	25	THE WITNESS: Can I get some water?	09:47

17 (Pages 62 to 65)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 66			Page 68		
1	MR. ANDERTON: Yes, you may get some	09:47	1	much at all.	09:50
2	water. Let's go off the record for a moment.	09:47	2	Q. Didn't do much at all. Did you meet	09:50
3	THE VIDEOGRAPHER: The time is 9:47 a.m.	09:47	3	with any of the lawyers for the Plaintiffs in this	09:50
4	We're going off the record briefly.	09:47	4	litigation Mr. Kerensky, Miss Johnson, any of	09:50
5	(Short break)	09:48	5	those lawyers?	09:50
6	THE VIDEOGRAPHER: The name is 9:48 a.m.	09:48	6	A. When you say "meet."	09:50
7	We are back on the record.	09:48	7	Q. Did you meet with them in person?	09:50
8	BY MR. ANDERTON:	09:48	8	A. No.	09:50
9	Q. Dr. Bliesner, I'm going to let you	09:48	9	Q. Did you speak to them on the telephone?	09:50
10	continue your review, but I'm going to briefly ask	09:48	10	A. I spoke with them but it didn't have	09:50
11	you a few questions.	09:48	11	much to do with prep.	09:50
12	Did you prepare for this deposition today?	09:48	12	Q. Did you speak to them on the telephone?	09:50
13	A. Some.	09:48	13	A. I did speak with Miss Johnson.	09:50
14	Q. What did you do to prepare?	09:48	14	Q. Miss Johnson?	09:50
15	A. At Mike's suggestion I took all of the	09:48	15	A. Yeah, briefly, and confirmed with	09:50
16	boxes and stuff that were disorganized from the	09:48	16	Mike -- I can never pronounce.	09:50
17	last deposition -- but I did nothing with them --	09:48	17	Q. Kerensky.	09:50
18	and put them in order.	09:48	18	A. Kerensky, yeah.	09:50
19	Q. Did you do anything else besides	09:48	19	MR. ANDERTON: I got your back, Mike.	09:50
20	organize your boxes?	09:48	20	MR. KERENSKY: Got it.	09:50
21	A. Reviewed the report.	09:48	21	BY MR. ANDERTON:	09:50
22	Q. You did review the report?	09:48	22	Q. You spoke with Miss Johnson how many	09:50
23	A. Uh-huh.	09:49	23	times?	09:50
24	Q. When did you do that?	09:49	24	A. Once.	09:50
25	A. This morning.	09:49	25	Q. How long did that conversation last?	09:50

Page 67			Page 69		
1	Q. This morning?	09:49	1	A. About a minute and a half.	09:51
2	A. Uh-huh.	09:49	2	Q. That was -- that was since January 25th,	09:51
3	Q. When you got here at 7:30 or so?	09:49	3	between January 25th and today?	09:51
4	A. Uh-huh.	09:49	4	A. No. You asked yesterday in preparation	09:51
5	Q. What time did you get up to review your	09:49	5	for this.	09:51
6	report this morning?	09:49	6	Q. No, I said before this deposition. I	09:51
7	A. I woke up at 3:30 this morning.	09:49	7	was not limiting my question to yesterday.	09:51
8	Q. Do you typically wake up at 3:30?	09:49	8	A. Okay. Before this deposition?	09:51
9	A. Unfortunately I have to say this, but	09:49	9	Q. Yeah. So let's break this down, okay,	09:51
10	yes, I do.	09:49	10	Dr. Bliesner.	09:51
11	Q. It is unfortunate.	09:49	11	A. Uh-huh.	09:51
12	A. Middle age.	09:49	12	Q. I need you to listen very carefully,	09:51
13	Q. Did you -- did you review the entire	09:49	13	please.	09:51
14	report this morning?	09:49	14	A. Right. I am.	09:51
15	A. No.	09:49	15	Q. Since you were -- since we began this	09:51
16	Q. Well, what parts of it did you review	09:49	16	deposition and opened the record on January 25th	09:51
17	and what the purpose of your reviewing the report	09:49	17	and up to today --	09:51
18	this morning, what were you looking for?	09:49	18	A. Okay.	09:51
19	A. Just glancing through, familiarize	09:49	19	Q. -- what did you do -- what have you done	09:51
20	myself with some of the attachments.	09:49	20	to prepare for today's session?	09:51
21	Q. Before organizing -- other than	09:49	21	A. What I said already. I organized my	09:51
22	organizing your boxes and reading your report this	09:49	22	papers and I reviewed the report. Preparation, if	09:51
23	morning, what else did you do to prepare for this	09:49	23	that's what you want to call it, for the -- with	09:51
24	deposition today?	09:49	24	Miss Johnson and Mr. Kerensky was just a matter of	09:51
25	A. Preparation, that was it. I didn't do	09:50	25	just show up and your organize your papers. I	09:51

18 (Pages 66 to 69)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 70			Page 72		
1	don't think you need to do much else. And you	09:51	1	A. I know this was prep per se. It's not	09:53
2	just do what you did last time.	09:52	2	like we sat down and spent hours going back and	09:53
3	Miss Johnson didn't provide any guidance	09:52	3	forth and discussing how I'm supposed to respond	09:53
4	whatsoever. She was in the process of looking up	09:52	4	to your questions or anything like that. It was	09:54
5	some additional documentation, but I never looked	09:52	5	just like are we on? Just organize your paper.	09:54
6	at it.	09:52	6	That stuff. Nothing detailed.	09:54
7	Q. How many times have you -- did you speak	09:52	7	Q. So you didn't have any discussion with	09:54
8	with Miss Johnson between January 25th and today?	09:52	8	Mr. Kerensky since January 25th about what	09:54
9	A. Specifically a number, I don't know.	09:52	9	happened on January 25th and what you might expect	09:54
10	Q. More than once?	09:52	10	to happen during this session?	09:54
11	A. Once, maybe.	09:52	11	A. Between January 25th and this morning?	09:54
12	Q. Twice?	09:52	12	Q. Yes.	09:54
13	A. Maybe. I don't think it was more than	09:52	13	A. Interestingly enough, I don't think I	09:54
14	two.	09:52	14	heard anything from him following the whole thing.	09:54
15	Q. Did you speak to her?	09:52	15	Q. Well, how many times did you speak to	09:54
16	A. Yesterday, yes, for sure.	09:52	16	him?	09:54
17	Q. Any time before yesterday and since	09:52	17	A. I said yesterday I know for sure. Maybe	09:54
18	January 25th?	09:52	18	one other time to coordinate the schedule and that	09:54
19	A. I don't recall.	09:52	19	was it.	09:54
20	Q. How about Mr. Kerensky? Did you speak	09:52	20	Q. Well, he told you to organize your	09:54
21	to him between January 25th and today?	09:52	21	papers. That's not coordinating the schedule, is	09:54
22	A. Well, yesterday, coordinated to get	09:52	22	it?	09:54
23	here.	09:52	23	A. It's -- it's what he told me to do. He	09:54
24	Q. Other than yesterday, have you spoken to	09:52	24	says don't worry necessarily about preps, words to	09:54
25	Mr. Kerensky since January 25th?	09:52	25	that effect. Just organize your papers so you	09:54
Page 71			Page 73		
1	A. Perhaps once.	09:52	1	don't flounder around and waste people's time.	09:54
2	Q. When?	09:53	2	Q. And how long was your conversation with	09:55
3	A. I don't recall specifically.	09:53	3	Mr. Kerensky?	09:55
4	Q. Was that a telephone conversation?	09:53	4	A. That particular one?	09:55
5	A. I -- I don't recall specifically. It	09:53	5	Q. Yeah.	09:55
6	was not what you would consider prep. It was just	09:53	6	A. Maybe a minute or two.	09:55
7	coordination.	09:53	7	Q. Were there other conversations before	09:55
8	Q. Dr. Bliesner, you need to answer my	09:53	8	yesterday and since January 25th besides that	09:55
9	questions.	09:53	9	minute or two conversation?	09:55
10	A. Uh-huh. I'm answering your questions.	09:53	10	A. There may have been one other, but it	09:55
11	Q. No, you're not. I asked you if you	09:53	11	was nothing extensive.	09:55
12	spoke to Mr. Kerensky. I didn't ask you to	09:53	12	Q. How long was it?	09:55
13	characterize the phone call yet.	09:53	13	A. If there was one, is was e-mail or	09:55
14	Have you spoken to Mr. Kerensky since January	09:53	14	whatever. Similar thing. Maybe a minute and a	09:55
15	25th?	09:53	15	half.	09:55
16	A. Yes.	09:53	16	Q. Well, was it a conversation or was it	09:55
17	Q. Was it a telephone conversation?	09:53	17	e-mail communication. Because I haven't asked	09:55
18	A. Yes.	09:53	18	about e-mails communications. I asked you about	09:55
19	Q. Have you met with Mr. Kerensky in person	09:53	19	conversations.	09:55
20	since January 25th?	09:53	20	A. I don't know. I'd have to go pull them	09:55
21	A. No.	09:53	21	out and look at them. All I know is none of these	09:55
22	Q. I mean we're only talking about three	09:53	22	conversations were substantive in terms of	09:55
23	weeks.	09:53	23	guidance or anything like that.	09:55
24	A. Yeah, I didn't.	09:53	24	Q. Dr. Bliesner, I am entitled to find out	09:55
25	Q. Okay.	09:53	25	how many there were, then we'll talk about the	09:55

19 (Pages 70 to 73)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 74			Page 76		
1	substance of them; okay?	09:55	1	A. I really honestly don't know.	10:09
2	A. I cannot tell you with certainty how	09:55	2	Q. Dr. Bliesner, we're talking about a	10:09
3	many telephone conversations or e-mails I had with	09:55	3	three-week period and you're -- as I've said --	10:09
4	them. I know that it was not a large number.	09:55	4	obviously a very intelligent, very organized	10:10
5	Q. Okay. So you know that it was more than	09:56	5	individual. Prepared a very extensive report in	10:10
6	one, though; correct?	09:56	6	this case, reviewed thousands of pages of	10:10
7	A. I can't say that with certainty. I	09:56	7	documents. I'm merely asking you how many times	10:10
8	really don't. My life is busy. I'm working 70,	09:56	8	you've spoken on the telephone to Mr. Kerensky in	10:10
9	80 hours a week on another consulting job. This	09:56	9	the last three weeks.	10:10
10	is minor in terms of coordination, get things	09:56	10	A. I honestly cannot tell you for sure.	10:10
11	done. I don't know. I can't say it explicitly.	09:56	11	Q. Have you spoken to any lawyers other	10:10
12	I'm not going to make stuff up to make you happy.	09:56	12	than Mr. Kerensky and Ms Johnson in the last three	10:10
13	Q. I'm not asking you to make me happy.	09:56	13	weeks?	10:10
14	I'm merely asking you to answer my questions	09:56	14	A. Yes.	10:10
15	truthfully.	09:56	15	Q. Who?	10:10
16	As we said earlier, you're a very intelligent	09:56	16	A. A gentleman out of Oklahoma.	10:10
17	man and we're only talking about a three-week	09:56	17	Q. Brad Miller?	10:10
18	period here.	09:56	18	A. Yes.	10:10
19	MR. KERENSKY: I think I need a break.	09:56	19	Q. When did you speak to Brad Miller?	10:10
20	MR. ANDERTON: Why do you need a break?	09:56	20	A. Yesterday.	10:10
21	MR. KERENSKY: I have to go to the	09:56	21	Q. What prompted that phone conversation	10:10
22	bathroom.	09:56	22	with Mr. Miller?	10:10
23	MR. ANDERTON: All right. All right.	09:56	23	A. Apparently he had the opportunity to	10:10
24	Let's go off the record.	09:56	24	review my report.	10:10
25	THE VIDEOGRAPHER: The time is	09:56	25	Q. And tell me about that conversation with	10:10
Page 75			Page 77		
1	9:56 p.m. -- we're going -- or a.m. We're	09:56	1	Mr. Miller.	10:10
2	going off the record.	09:56	2	A. He was just curious of -- my involvement	10:11
3	(Short break)	10:08	3	in the -- in this case.	10:11
4	THE VIDEOGRAPHER: The time is . We	10:08	4	Q. How long did the phone conversation last	10:11
5	are back on the record. This is the beginning	10:08	5	with Mr. Miller, yesterday?	10:11
6	of tape three.	10:08	6	A. Maybe a half an hour.	10:11
7	MR. ANDERTON: Mike, are you with us?	10:09	7	Q. So what did you discuss with Mr. Miller	10:11
8	MR. KERENSKY: I am.	10:09	8	during that 30-minute or so phone conversation?	10:11
9	BY MR. ANDERTON:	10:09	9	A. What I did for a living primarily.	10:11
10	Q. All right. Dr. Bliesner, before	10:09	10	Q. Yeah.	10:11
11	Mr. Kerensky's break or requested break, we were	10:09	11	A. And a few things about the report.	10:11
12	discussing what you've done to prepare for today's	10:09	12	Q. Such as? Mike? Mike? Mike?	10:11
13	session and I just want to remind you of something	10:09	13	MR. KERENSKY: Yes, sorry, sorry, sorry.	10:11
14	we agreed earlier in the day and that is that you	10:09	14	BY MR. ANDERTON:	10:12
15	would focus very hard on the questions that I ask	10:09	15	Q. A few things about the report,	10:12
16	and do your best to actually answer those	10:09	16	Dr. Bliesner. Such as what?	10:12
17	questions.	10:09	17	A. The conclusions that were in there.	10:12
18	A. I understand.	10:09	18	That was it primarily.	10:12
19	Q. Okay. So I'm going to go back into some	10:09	19	Q. Well tell me about that discussion with	10:12
20	of that subject.	10:09	20	Mr. Miller about the conclusions that were in	10:12
21	A. Okay.	10:09	21	there.	10:12
22	Q. How many times have you spoken to	10:09	22	A. Just what's written in the report. My	10:12
23	Mr. Kerensky on the telephone since January 25th?	10:09	23	conclusions with respect to compliance and those	10:12
24	A. I really honestly don't know.	10:09	24	kinds of things. It wasn't a very specific	10:12
25	Q. Is it more than just yesterday?	10:09	25	discussion. It was more about my work background,	10:12

20 (Pages 74 to 77)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 78		Page 80	
1	what I'd done, what I do now, things like that. 10:12	1	your report? 10:14
2	Q. Well, I want to know what you discussed 10:12	2	A. Yes. 10:14
3	with him with respect to the conclusion in your 10:12	3	Q. Are the documents in these boxes that 10:14
4	report. Tell me about that conversation. It was 10:12	4	you read and reviewed after you wrote and 10:14
5	just yesterday. 10:12	5	submitted the report -- the date of your report is 10:14
6	A. Yes. 10:12	6	June 15, 2010. 10:14
7	Q. So tell me about that conversation. 10:12	7	A. This would be the only one. This is the 10:14
8	A. Basically said you have the report, the 10:12	8	deposition. 10:14
9	conclusions that I have come to in the report are 10:12	9	Q. Of? 10:14
10	supported by the documents that are in the 10:12	10	A. Of last time we met. It was sent to me, 10:14
11	attachment. That's how I did the review. 10:12	11	but I need to review. I haven't gotten all the 10:15
12	Q. What kind of questions did Mr. Miller 10:12	12	way through it. 10:15
13	ask you with respect to the conclusions in your 10:12	13	Q. So the transcript of January 25th? 10:15
14	report yesterday? 10:12	14	A. Yes. 10:15
15	A. I think he asked me if I reviewed any 10:13	15	Q. Your deposition proceedings? 10:15
16	additional documents since I wrote the report. 10:13	16	A. Yes. 10:15
17	Q. What did you tell him? 10:13	17	Q. Is that the only document that you have 10:15
18	A. I said additional documents, no. It was 10:13	18	reviewed that relates to this litigation and to 10:15
19	just like I told you. I just prepared for this 10:13	19	your report since you wrote the report? 10:15
20	and then organized them, so... 10:13	20	A. No. Because you also asked me to get 10:15
21	Q. Well, you didn't tell me that you 10:13	21	what my hourly rate was and the billing records. 10:15
22	prepared for this. 10:13	22	Q. Okay. 10:15
23	A. Well, what I did to get ready for this 10:13	23	A. So those are the things. 10:15
24	was organize my mass of documents after the last 10:13	24	Q. Other than your billing records and the 10:15
25	thing so I wouldn't waste time. 10:13	25	transcript of the January 25th session, are there 10:15
Page 79		Page 81	
1	Q. Okay. And so he asked you what 10:13	1	any other documents that you've reviewed that 10:15
2	additional documents or whether you had reviewed 10:13	2	relate to this litigation and to the report issued 10:15
3	any additional documents. You told Mr. Miller you 10:13	3	in this litigation since June 15, 2010? 10:15
4	had not reviewed any additional documents since 10:13	4	A. Since June 15th? 10:15
5	you wrote the report? 10:13	5	Q. Since you submitted your report. 10:15
6	A. I'm pretty sure that's what I told him. 10:13	6	A. Uh-huh. I can't recall if there were 10:15
7	Q. Well, let me ask you -- 10:13	7	any specific additional documents. I don't 10:16
8	A. Uh-huh. 10:13	8	believe there were. Because when the report was 10:16
9	Q. -- have you reviewed any additional 10:13	9	done, I was pretty much checked out and 10:16
10	documents since you wrote the report? 10:14	10	concentrating on a current client. 10:16
11	A. Other than what was already present -- 10:14	11	Q. When Mr. Miller asked you that question 10:16
12	what I did the last time, no, I have not. 10:14	12	yesterday, is that what you told him as well, that 10:16
13	Q. What do you mean by other than what you 10:14	13	you can't recall? 10:16
14	did the last time. 10:14	14	A. He didn't explicitly ask the question 10:16
15	A. This stuff. All of these documents that 10:14	15	like you did. 10:16
16	are in here. 10:14	16	Q. What did he ask? 10:16
17	Q. The documents that are in there -- and 10:14	17	A. He said have you reviewed any additional 10:16
18	so that we're clear, Dr. Bliesner, you're pointing 10:14	18	documentation. 10:16
19	to boxes that you brought with you; correct? 10:14	19	Q. And what did you say? 10:16
20	A. Uh-huh. 10:14	20	A. I said not that I remember. 10:16
21	Q. Those are documents you had reviewed as 10:14	21	Q. What else did Mr. Miller ask you? 10:16
22	you wrote the report or as you were in the process 10:14	22	A. That was about it. 10:16
23	of writing the report; is that correct? 10:14	23	Q. Well, it was a 30-minute conversation, 10:16
24	A. Yes. The supporting data for this. 10:14	24	Dr. Bliesner. And it doesn't take 30 minutes to 10:16
25	Q. "The supporting data for this" meaning 10:14	25	ask you if you reviewed additional documents and 10:16

21 (Pages 78 to 81)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

<p style="text-align: right;">Page 82</p> <p>1 to talk about the background of the work that you 10:16</p> <p>2 do. So what else did Mr. Miller ask you yesterday 10:16</p> <p>3 when you spoke with him? 10:16</p> <p>4 A. We talked about -- just to get 10:16</p> <p>5 acquainted, talked about my other two companies. 10:16</p> <p>6 Q. Did you talk about your deposition 10:17</p> <p>7 today? 10:17</p> <p>8 A. I did mention to him that I went through 10:17</p> <p>9 it. 10:17</p> <p>10 Q. That you were? 10:17</p> <p>11 A. Today's? 10:17</p> <p>12 Q. Yes. 10:17</p> <p>13 A. No, no. But the one before, yeah. 10:17</p> <p>14 Q. Did you talk about your January 25th 10:17</p> <p>15 session with him? 10:17</p> <p>16 A. A little, yes. 10:17</p> <p>17 Q. What did you talk about with him with 10:17</p> <p>18 respect to the January 25th deposition session? 10:17</p> <p>19 A. How difficult it was because I've never 10:17</p> <p>20 done anything like this before. 10:17</p> <p>21 Q. Why do you think it's difficult? 10:17</p> <p>22 A. It's just a different way of doing 10:17</p> <p>23 business than anything I've ever seen before. 10:17</p> <p>24 Q. In what way? 10:17</p> <p>25 A. That's a good question. 10:17</p>	<p style="text-align: right;">Page 84</p> <p>1 Q. And were you told to make it so when you 10:19</p> <p>2 prepared for your first deposition session? 10:19</p> <p>3 A. Told what, sir? 10:19</p> <p>4 Q. Well, I'm going to hand you -- and I 10:19</p> <p>5 don't have a stapler so this isn't stapled. 10:19</p> <p>6 A. Uh-huh. 10:19</p> <p>7 Q. We marked this last time as -- 10:19</p> <p>8 A. Yes. 10:19</p> <p>9 Q. -- Exhibit 109. 10:19</p> <p>10 A. Yes. 10:19</p> <p>11 Q. Do you see that, Dr. Bliesner? 10:19</p> <p>12 A. I do. 10:19</p> <p>13 Q. Tell me what it is. Mike. Typing. 10:19</p> <p>14 MR. KERENSKY: I'm sorry. 10:19</p> <p>15 THE WITNESS: This is my notes of 25 10:19</p> <p>16 January. Yeah, outlines a condensation of 10:19</p> <p>17 points that are listed in the report, some 10:19</p> <p>18 scratching with respect to calculation that we 10:20</p> <p>19 were talking about. 10:20</p> <p>20 BY MR. ANDERTON: 10:20</p> <p>21 Q. And you actually made the body notes on 10:20</p> <p>22 page 1 during your last deposition; right? 10:20</p> <p>23 A. Bottom one, yes, yes. Yeah, that was 10:20</p> <p>24 the thickness discussion if I recall properly. 10:20</p> <p>25 Q. All right. 10:20</p>
<p style="text-align: right;">Page 83</p> <p>1 Q. Every so often I try to come up with a 10:17</p> <p>2 good one. 10:17</p> <p>3 A. I'm used to collaborative conversations 10:17</p> <p>4 not combative conversations. 10:17</p> <p>5 Q. I don't intend for this to be a 10:18</p> <p>6 combative conversation. Do you intend for this to 10:18</p> <p>7 be a combative conversation? 10:18</p> <p>8 A. Absolutely not. 10:18</p> <p>9 Q. Do you think this is a combative 10:18</p> <p>10 conversation? 10:18</p> <p>11 A. It's not fun. I can tell you that. 10:18</p> <p>12 Q. Well, just because it's not fun doesn't 10:18</p> <p>13 mean it's combative, does it? 10:18</p> <p>14 A. I suppose not. 10:18</p> <p>15 Q. Do you think this is a combative 10:18</p> <p>16 conversation or a combative process? 10:18</p> <p>17 MR. KERENSKY: I think you can be that 10:18</p> <p>18 way, Mike. But let's try and ask some real 10:18</p> <p>19 questions about the case. 10:18</p> <p>20 BY MR. ANDERTON: 10:18</p> <p>21 Q. I'm waiting for an answer, Dr. Bliesner. 10:18</p> <p>22 A. I don't know if combative is the right 10:18</p> <p>23 word for it, but it's not the give and take, 10:18</p> <p>24 casual problem-solving in an open environment that 10:18</p> <p>25 I'm used to in my workplaces. 10:18</p>	<p style="text-align: right;">Page 85</p> <p>1 A. Uh-huh. 10:20</p> <p>2 Q. So, let's go to page 2. 10:20</p> <p>3 A. Okay. 10:20</p> <p>4 Q. What are those? 10:20</p> <p>5 A. Guidance from Mr. Kerensky on how things 10:20</p> <p>6 would go generally in a deposition because I've 10:20</p> <p>7 never been in one like this, so... 10:20</p> <p>8 Q. These are notes that you made -- 10:20</p> <p>9 A. Uh-huh. 10:20</p> <p>10 Q. -- of a conversation? You have to 10:20</p> <p>11 answer yes or no, Doctor. 10:20</p> <p>12 A. Oh, I'm sorry. Yes. 10:20</p> <p>13 Q. Of a conversation you had with 10:20</p> <p>14 Mr. Kerensky? 10:20</p> <p>15 A. And Mr. Miller and the other gentleman 10:20</p> <p>16 that was with them, the other attorney. 10:20</p> <p>17 Q. Mr. Thompson, Fred Thompson? 10:20</p> <p>18 A. No, no, no. This was the day before 10:20</p> <p>19 the -- 10:21</p> <p>20 MR. KERENSKY: I think it was Terry 10:21</p> <p>21 Kilpatrick. 10:21</p> <p>22 MR. ANDERTON: Terry Kilpatrick? 10:21</p> <p>23 THE WITNESS: Yeah. 10:21</p> <p>24 MR. KERENSKY: Meghan was there, too. 10:21</p> <p>25 THE WITNESS: Meghan, yeah, was there 10:21</p>

22 (Pages 82 to 85)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 86			Page 88		
1	too.	10:21	1	deposition.	10:23
2	BY MR. ANDERTON:	10:21	2	Q. So January 24th.	10:23
3	Q. So there were four lawyers there:	10:21	3	A. I believe that was the date, yes.	10:23
4	Mr. Kerensky, Mr. Miller, Ms Johnson, and	10:21	4	Q. Did you meet with the lawyers for the	10:23
5	Mr. Kilpatrick.	10:21	5	Plaintiffs in person to prepare for the January	10:23
6	A. Yes.	10:21	6	25th deposition other than on January 24?	10:23
7	Q. Who told you to answer questions as	10:21	7	A. To prepare for the deposition?	10:23
8	briefly as possible, to give no more or no less	10:21	8	Q. Yes.	10:23
9	than is needed?	10:21	9	A. No.	10:23
10	A. I believe that they -- all of the people	10:21	10	Q. Did you talk to them on the telephone,	10:23
11	in that room gave that guidance if I recall.	10:21	11	any of them, to prepare for the deposition other	10:23
12	Q. One of your notes here says, "saying no	10:21	12	than on January 24th?	10:24
13	closes the door." What does that mean? Well,	10:21	13	A. I can't recall specifically.	10:24
14	what does it mean?	10:21	14	Q. You don't remember whether you even had	10:24
15	A. If there is additional information that	10:21	15	a conversation with them?	10:24
16	needs to come out that would clarify the	10:21	16	A. No, I don't. I have conversations with	10:24
17	situation, you can just go no. Then you're not	10:21	17	people day in and day out and this is just one	10:24
18	going to have that conversation again. So -- as I	10:21	18	small part of it. I can't recall.	10:24
19	understood the guidance.	10:22	19	Q. Well, you had to make arrangements to	10:24
20	Q. Who -- well, whose term is "closes the	10:22	20	meet with them on the 24th; correct?	10:24
21	door." Who said that to you?	10:22	21	A. Yes.	10:24
22	A. I don't know which one specifically.	10:22	22	Q. So you had to have some communication.	10:24
23	This is a whole new process for me at this stage	10:22	23	Do you think that was by telephone?	10:24
24	of the game so I was just listening.	10:22	24	A. Perhaps and perhaps e-mail. I have to	10:24
25	Q. What does it mean, "keep doors open."	10:22	25	go back and look at them.	10:24
Page 87			Page 89		
1	What does that mean?	10:22	1	Q. Well, would you have those e-mails with	10:24
2	A. If there's line of questions that would	10:22	2	you?	10:24
3	add clarification to the conversation, I want to	10:22	3	A. I believe I gave all of those to Miss	10:24
4	make sure that they stay open. Just saying no, it	10:22	4	Johnson. We copied them over off of an external	10:24
5	stops conversation potentially in the future.	10:22	5	hard drive and she has them.	10:25
6	Q. And your notes say "yes, but" and what I	10:22	6	Q. She has them?	10:25
7	will call ellipses and "no, but" with another	10:22	7	A. Huh-huh.	10:25
8	ellipses. What do those notes mean?	10:22	8	Q. Do you have them?	10:25
9	A. Those are with respect to, for instance,	10:22	9	A. No.	10:25
10	if you would ask a question that was very narrow	10:22	10	Q. Do you have the hard drive with you?	10:25
11	that didn't necessarily include the additional	10:22	11	A. Yes.	10:25
12	information that I felt would be appropriate to	10:22	12	Q. May I see it, please?	10:25
13	explain the situation, "but" let's me continue on	10:22	13	A. Sure.	10:25
14	to give the additional information to clarify the	10:22	14	Q. Let's go back to your conversation	10:25
15	point.	10:23	15	yesterday with Brad Miller.	10:25
16	Q. So you don't believe in answering --	10:23	16	A. Okay.	10:25
17	they told you not to answer a narrowly crafted	10:23	17	Q. How did he come to have your contact	10:25
18	question with a narrow answer; is that right?	10:23	18	information, do you know?	10:25
19	A. I don't think I got that specific	10:23	19	A. I believe he said Pete Miller and he had	10:25
20	guidance.	10:23	20	interacted. I believe that's what he said.	10:25
21	Q. Well, I was merely following up on your	10:23	21	Q. Did -- did Mr. Miller -- Brad Miller,	10:25
22	response a moment ago, Dr. Bliesner.	10:23	22	since we now have two Millers -- did Brad Miller	10:25
23	These notes are from a meeting that occurred	10:23	23	yesterday -- did you and he discuss the	10:25
24	when?	10:23	24	possibility of him retaining you as an expert in	10:26
25	A. That was the day before we had the first	10:23	25	his case?	10:26

23 (Pages 86 to 89)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 90			Page 92		
1	A. We did have that conversation.	10:26	1	Q. Do you anticipate that you're going to	10:28
2	Q. And tell me about that conversation.	10:26	2	talk to him again?	10:28
3	A. He asked me, you know, whether I was	10:26	3	A. Perhaps.	10:28
4	interested potentially in doing it.	10:26	4	Q. Let's go back to what you did to	10:28
5	MR. KERENSKY: I need to interrupt for a	10:26	5	prepare.	10:29
6	second. We may be treading into a violation	10:26	6	The -- before January 25th, we know that you	10:29
7	of the consulting expert privilege.	10:26	7	met with Mr. Kerensky and several other folks to	10:29
8	MR. ANDERTON: Well, okay.	10:26	8	prepare for the session the next day. How long	10:29
9	MR. KERENSKY: Because I don't know if	10:26	9	did that meeting on January 24th last?	10:29
10	Brad hired him or not hired him. At this	10:26	10	A. I think last time I said it was	10:29
11	point, I think that would make him a	10:26	11	something in the neighborhood of four, five hours,	10:29
12	consulting expert. Since I'm here not for --	10:26	12	something like that.	10:29
13	I'm here for Miss Vega, but I think the	10:26	13	Q. Did you --	10:29
14	witness should be advised that conversations	10:26	14	A. That I recall.	10:29
15	prior to being retained by a Plaintiff's	10:26	15	Q. I asked you a moment ago if you met with	10:29
16	lawyer are confidential and protected and	10:26	16	any of those Plaintiffs' lawyers in person other	10:29
17	privileged under what we call the consulting	10:26	17	than on January 24th. Your testimony was no, you	10:29
18	expert rule. And until you're retained and	10:26	18	did not; correct?	10:29
19	disclosed as a testifying expert, those	10:26	19	A. For preparation with the deposition.	10:29
20	conversations are privileged. And I guess I	10:27	20	Q. You met with them in person as you	10:29
21	will assert that privilege on behalf of Mr. --	10:27	21	prepared your report?	10:29
22	is it Miller, Brad Miller?	10:27	22	A. Yes, one time.	10:29
23	THE WITNESS: Yes.	10:27	23	Q. Where was that?	10:30
24	MR. KERENSKY: Okay.	10:27	24	A. In Indian Rocks Beach.	10:30
25	MR. ANDERTON: Well, Mike, I'm not sure I	10:27	25	Q. They came to see you?	10:30

Page 91			Page 93		
1	agree with your characterization of the	10:27	1	A. Uh-huh.	10:30
2	privilege and I hope that you're not making a	10:27	2	Q. Yes or no?	10:30
3	representation of Oklahoma law with respect to	10:27	3	A. They came to see me. Yes. Sorry.	10:30
4	expert privileges, are you?	10:27	4	Q. That's all right.	10:30
5	MR. KERENSKY: Oh, I think it's in the	10:27	5	A. Sorry.	10:30
6	federal rules, consulting experts.	10:27	6	Q. I'm just trying to make sure that the.	10:30
7	MR. ANDERTON: Well, you are aware	10:27	7	A. Yes.	10:30
8	Mr. Kerensky of course that the case	10:27	8	Q. Videographer and court reporter --	10:30
9	Mr. Miller is discussing with Dr. Bliesner --	10:27	9	A. It actually wasn't in preparation of	10:30
10	with Dr. Bliesner is not a federal case;	10:27	10	the -- well, it wasn't writing the report. They	10:30
11	right.	10:27	11	just delivered more documents to me.	10:30
12	MR. KERENSKY: Well, I'm guessing that	10:27	12	Q. In person?	10:30
13	Oklahoma law probably has the same privileges	10:27	13	A. Uh-huh.	10:30
14	as every other state I've been in. So no	10:28	14	Q. That's awfully nice of them.	10:30
15	doubt I'm guessing but I want to make sure	10:28	15	A. Uh-huh.	10:30
16	that I assert the privilege to the extent it	10:28	16	Q. Who did that?	10:30
17	exists. During the case I'm sure you've	10:28	17	A. Who was there?	10:30
18	updated yourself on the rules and know one way	10:28	18	Q. Yeah, who delivered the documents?	10:30
19	or the other whether it exists. And I just	10:28	19	A. It was Pete Miller and Meghan Johnson	10:30
20	think I owe it to him to assert it at this	10:28	20	Carter.	10:30
21	time.	10:28	21	Q. How long -- did you have a meeting with	10:30
22	MR. ANDERTON: Okay.	10:28	22	them when they delivered more documents?	10:30
23	BY MR. ANDERTON:	10:28	23	A. They actually came over to my home	10:30
24	Q. Have you been retained by Brad Miller?	10:28	24	office.	10:30
25	A. No.	10:28	25	Q. So did you have a meeting with them?	10:30

24 (Pages 90 to 93)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 94			Page 96		
1	A. If you'd call it a meeting, yes.	10:30	1	A. That's all I'm trying to do.	10:33
2	Q. How long?	10:30	2	Q. You were asked to bring them with you	10:33
3	A. I honestly have to go back and look it	10:30	3	today. Did you not double check to make sure you	10:33
4	up.	10:30	4	had all the records you were supposed to bring?	10:33
5	Q. Did you bring your billing and time	10:30	5	A. I forwarded them via e-mail to	10:33
6	records with you?	10:30	6	Mr. Miller and Mr. -- Miss Johnson before. So I	10:33
7	A. Yes, I did.	10:30	7	made the assumption that they forwarded them to	10:33
8	Q. May I see them?	10:30	8	you.	10:33
9	A. Sure.	10:30	9	Q. They did not.	10:33
10	Q. Phil, you want to mark those, please?	10:31	10	A. Okay	10:33
11	Let's call it 145 please.	10:31	11	Q. And you know that you were asked to	10:33
12	(Whereupon, Exhibit 145 was marked for	10:31	12	bring them with you today; right?	10:33
13	identification)	10:31	13	A. Yes, yes.	10:33
14	Dr. Bliesner, I'm looking at a document that	10:31	14	Q. So --	10:33
15	has been marked as Exhibit 145.	10:31	15	A. I brought a copy because I thought that	10:33
16	A. Uh-huh.	10:31	16	you got them all.	10:33
17	Q. And it is a stack of invoices that you	10:31	17	Q. I have got nothing.	10:33
18	just handed me; is that correct?	10:31	18	A. Okay.	10:33
19	A. I guess it is.	10:32	19	Q. From any of the lawyers and Plaintiffs.	10:33
20	Q. Is this all of the invoices that you	10:32	20	A. Okay.	10:33
21	have submitted to Plaintiffs' counsel for your	10:32	21	Q. Or any of the Plaintiffs' lawyers.	10:33
22	services as an expert witness? Dr. Bliesner, you	10:32	22	A. Okay.	10:33
23	just handed -- I asked you if you had --	10:32	23	Q. That's why we asked you to bring them.	10:33
24	A. Yes.	10:32	24	A. Okay.	10:33
25	Q. -- your billing records.	10:32	25	Q. You understood that you were supposed to	10:33
Page 95			Page 97		
1	A. I don't do the billing so I don't know	10:32	1	bring all of your billing records today; correct?	10:33
2	if these are all of the invoices. I was looking	10:32	2	A. Not specifically because I'd already	10:33
3	for the last date on here.	10:32	3	provided them. I just brought this because this	10:33
4	Q. You were asked to bring them with you.	10:32	4	is the hard copy that I had I scanned in e-mail,	10:33
5	A. Yes.	10:32	5	so...	10:34
6	Q. I just asked you if you brought them.	10:32	6	Q. When did you provide them to Plaintiffs'	10:34
7	You said yes.	10:32	7	counsel? After January 25th?	10:34
8	A. Yes, sir.	10:32	8	A. Yes. At your request.	10:34
9	Q. In response I said may I see them and	10:32	9	Q. Okay. I guess then you have to look	10:34
10	you said yes.	10:32	10	through that stack of documents and take up more	10:34
11	A. Yes.	10:32	11	of our time looking at something that you should	10:34
12	Q. And then you handed me a stack of	10:32	12	know because you should have been prepared to	10:34
13	documents.	10:32	13	bring them with you today, but if you need to,	10:34
14	A. Yes, sir.	10:32	14	please do.	10:34
15	Q. Are you now looking at them as though	10:32	15	MR. KERENSKY: Objection, form.	10:34
16	you're not sure whether you actually brought the	10:32	16	MR. ANDERTON: Proceed, Dr. Bliesner.	10:34
17	right records with you? What are you doing?	10:32	17	THE WITNESS: This does not include last,	10:35
18	A. Well, you said "all records"; okay.	10:32	18	the 25th's billing.	10:35
19	Q. I said are they all of the invoices.	10:32	19	BY MR. ANDERTON:	10:35
20	A. All the invoices. I Am not sure because	10:32	20	Q. Have you invoiced Plaintiffs' counsel	10:35
21	I prepared this stack immediately after the last	10:32	21	for that -- for the time that you spent preparing	10:35
22	deposition at your request. I'm not sure whether	10:32	22	for and participating in the January 25th	10:35
23	that deposition invoice was included in this	10:33	23	deposition?	10:35
24	stack. See what I'm saying?	10:33	24	A. I don't know because I don't do it.	10:35
25	Q. Okay.	10:33	25	Q. Dr. Bliesner, I see -- did you review	10:35

25 (Pages 94 to 97)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 98		Page 100	
1	these documents before you came here today? 10:35	1	doesn't have the headers on it or not so I can't 10:37
2	A. That stack? 10:35	2	say definitively. On something like this normally 10:37
3	Q. Yes. 10:35	3	for a business transaction -- because I would like 10:37
4	A. No. 10:35	4	to be accurate in an e-mail -- I create a Word 10:37
5	Q. The first invoice indicates a rate of 10:35	5	document first, do spell check and everything else 10:37
6	\$350. It's dated January 16, 2010, \$350 per 10:35	6	and I cut and paste it in an e-mail. 10:37
7	hour. And the next invoice dated a week later, 10:35	7	Q. So you copy the text? 10:38
8	January 23rd, indicates a rate of \$550 per hour. 10:35	8	A. Yes. 10:38
9	Did your rate go up? 10:35	9	Q. And paste it into an e-mail? 10:38
10	A. There was a misunderstanding on the rate 10:35	10	A. Yes, sir. 10:38
11	to begin with. 10:36	11	Q. So that means that -- well, did you send 10:38
12	Q. Whose misunderstanding? 10:36	12	this -- the contents of the document that is 10:38
13	A. The Miller Law Firm. 10:36	13	marked as 146 to Mr. Miller? 10:38
14	Q. You sent the invoice out. 10:36	14	A. I did. 10:38
15	A. Yes. 10:36	15	Q. In what form? 10:38
16	Q. So whose misunderstanding? 10:36	16	A. In e-mail. 10:38
17	A. This was the additional -- I thought 10:36	17	Q. Do you have that e-mail with you? 10:38
18	that you received that as well but apparently not. 10:36	18	A. I do not. 10:38
19	Q. As I've said, I've not received anything 10:36	19	Q. Why not? 10:38
20	from Plaintiffs about -- 10:36	20	A. Because I gave all the e-mails to Miss 10:38
21	A. Uh-huh. 10:36	21	Johnson Carter. 10:38
22	Q. -- your communications with them -- 10:36	22	Q. May I see that, please? 10:38
23	A. Uh-huh. 10:36	23	A. Sure. 10:38
24	Q. -- your billing records -- 10:36	24	Q. So you sent an e-mail to Mr. Miller 10:38
25	A. Uh-huh. 10:36	25	somewhere around January 4, 2010, with the 10:38
Page 99		Page 101	
1	Q. -- anything. 10:36	1	following text or that includes the following 10:38
2	A. Uh-huh. 10:36	2	text. As discussed, my rates are, and then you 10:38
3	Q. So you just handed me a document that 10:36	3	list your rates. 10:38
4	Phil is going to mark as Exhibit 146. 10:36	4	A. Uh-huh. 10:38
5	A. Uh-huh. 10:36	5	Q. \$350 an hour for standard document 10:38
6	Q. Please, Phil. Thank you, sir. 10:36	6	review, on-site time, consultations, etc. 10:38
7	A. And this was prior to being retained 10:37	7	A. Uh-huh. 10:38
8	obviously. 10:37	8	Q. \$450 an hour for testimonies or 10:38
9	Q. Prior to being retained. 10:37	9	depositions? 10:38
10	A. Yes. 10:37	10	A. Uh-huh. 10:39
11	(Whereupon, Exhibit 146 was marked for 10:37	11	Q. Is that right? Is that correct? 10:39
12	identification) 10:37	12	A. Is that what it says there? Yes. 10:39
13	Q. So I'm reading a letter that says -- 10:37	13	Q. And \$550 involving for any cases 10:39
14	well, tell me what this is, 146. Is it an e-mail, 10:37	14	involving capital crimes. 10:39
15	is it a letter, what is it? 10:37	15	A. Uh-huh. 10:39
16	A. This is -- I believe it is a Word 10:37	16	Q. You have to say yes or no. 10:39
17	document that I cut and paste into e-mail. So I 10:37	17	A. Yes, sorry. 10:39
18	can -- I design a document first. 10:37	18	Q. That's all right. 10:39
19	Q. Okay. 10:37	19	A. I'll get this some day. 10:39
20	A. And I put it in an e-mail. So this is 10:37	20	Q. So the first invoice you submitted was 10:39
21	what that is. 10:37	21	at the \$350 per hour rate? 10:39
22	Q. That's just a Word document? 10:37	22	A. Yes. 10:39
23	A. I'm thinking it is. 10:37	23	Q. And every invoice thereafter was at the 10:39
24	Q. You're thinking it is? 10:37	24	\$550 per hour rate. 10:39
25	A. Yeah. I'm not sure; okay? Because it 10:37	25	A. Yes. 10:39

26 (Pages 98 to 101)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

<p style="text-align: right;">Page 102</p> <p>1 Q. Does this case involve a capital crime? 10:39</p> <p>2 A. Well, it involved a death potentially. 10:39</p> <p>3 So that wasn't necessarily explained to me when I 10:39</p> <p>4 was doing the initial consultation. 10:39</p> <p>5 Q. So you quoted your rate as \$550 per hour 10:39</p> <p>6 for a case involving a capital crime? 10:39</p> <p>7 A. A death, potentially. A capital crime, 10:39</p> <p>8 I don't know the legal term. So that's the term I 10:39</p> <p>9 used. 10:39</p> <p>10 Q. Oh, you used capital crime to indicate a 10:39</p> <p>11 death? 10:39</p> <p>12 A. Anything that involved potentially a 10:39</p> <p>13 death, yes. I'm not a lawyer. It's just a term 10:39</p> <p>14 that I came up with. 10:39</p> <p>15 Q. Had you ever been involved -- you've 10:39</p> <p>16 never been an expert witness before. 10:40</p> <p>17 A. No, absolutely not. This is all brand 10:40</p> <p>18 new stuff for me. So there was confusion on that 10:40</p> <p>19 and it turns out that there was potentially 10:40</p> <p>20 somebody that was hurt, so the rate was increased 10:40</p> <p>21 to 550. 10:40</p> <p>22 Q. You misunderstood that there was 10:40</p> <p>23 potentially somebody who was hurt? 10:40</p> <p>24 A. It was never specifically told to me 10:40</p> <p>25 that, you know, it was put to me we've got a case 10:40</p>	<p style="text-align: right;">Page 104</p> <p>1 THE WITNESS: Prior to the retention. 10:41</p> <p>2 BY MR. ANDERTON: 10:41</p> <p>3 Q. You have now been disclosed -- 10:41</p> <p>4 A. Uh-huh. 10:41</p> <p>5 Q. -- as a testifying expert. 10:41</p> <p>6 A. Uh-huh. 10:41</p> <p>7 Q. So even if Mr. Kerensky's 10:41</p> <p>8 characterization of the privilege is accurate, all 10:41</p> <p>9 communications you've had with counsel for 10:41</p> <p>10 Plaintiffs are open to my examination. 10:41</p> <p>11 A. Okay. 10:41</p> <p>12 Q. Okay. 10:41</p> <p>13 A. Okay. 10:41</p> <p>14 MR. KERENSKY: If it is about cases that 10:41</p> <p>15 you've been retained, if there is a file you 10:41</p> <p>16 have been retained on, he's right. Everything 10:41</p> <p>17 you talked to the PSC about or anything like 10:41</p> <p>18 that, that's fair game. 10:41</p> <p>19 MR. ANDERTON: And that's what we're 10:41</p> <p>20 discussing, Mike. You'll see when you see 10:41</p> <p>21 Exhibit 146 that it is communication between 10:41</p> <p>22 Dr. Bliesner and Pete Miller. 10:41</p> <p>23 MR. KERENSKY: Okay. That's great. 10:41</p> <p>24 THE WITNESS: Okay. 10:41</p> <p>25 BY MR. ANDERTON: 10:41</p>
<p style="text-align: right;">Page 103</p> <p>1 going on, something like this. I do have a 10:40</p> <p>2 question, though, you know? This is falling into 10:40</p> <p>3 pre, you know, retainer and stuff like that. Do I 10:40</p> <p>4 have the same right not to discuss the details 10:40</p> <p>5 here? 10:40</p> <p>6 MR. ANDERTON: Well, Mr. Kerensky -- like 10:40</p> <p>7 I said, I disagree with Mr. Kerensky's 10:40</p> <p>8 characterization of the scope of that 10:40</p> <p>9 privilege. 10:40</p> <p>10 THE WITNESS: Right. 10:40</p> <p>11 MR. ANDERTON: So... 10:40</p> <p>12 THE WITNESS: I'm not particularly 10:40</p> <p>13 comfortable talking about negotiations that I 10:40</p> <p>14 had with somebody prior to being put on 10:40</p> <p>15 retainer. 10:40</p> <p>16 MR. ANDERTON: I mean no disrespect, 10:40</p> <p>17 Dr. Bliesner. Whether you're comfortable or 10:40</p> <p>18 not, it's something I'm allowed to inquire 10:40</p> <p>19 into. 10:40</p> <p>20 MR. KERENSKY: Wait a minute. We're 10:40</p> <p>21 talking about -- I lost track of you guys. 10:41</p> <p>22 You're not talking back again about another 10:41</p> <p>23 case other than -- 10:41</p> <p>24 MR. ANDERTON: No, no. We're talking 10:41</p> <p>25 about his retention. 10:41</p>	<p style="text-align: right;">Page 105</p> <p>1 Q. So -- and why aren't you comfortable 10:41</p> <p>2 discussing negotiations you had? 10:41</p> <p>3 A. It's just bad business to talk to other 10:41</p> <p>4 people about negotiations in business with your 10:42</p> <p>5 clients. 10:42</p> <p>6 Q. Well, this isn't business, 10:42</p> <p>7 Dr. Bliesner. This is testimony in a legal 10:42</p> <p>8 proceeding. You understand that; right? 10:42</p> <p>9 A. I agree of course, but it's a 10:42</p> <p>10 transaction. 10:42</p> <p>11 Q. Dr. Bliesner, did you receive a notice 10:42</p> <p>12 of today's proceeding? 10:42</p> <p>13 A. Today's proceeding? 10:42</p> <p>14 Q. Yes. 10:42</p> <p>15 A. I received a notice for the one on the 10:42</p> <p>16 25th, but one specifically for today? 10:42</p> <p>17 Q. Yeah. 10:42</p> <p>18 A. Not that I recall. 10:42</p> <p>19 Q. Not that you recall. 10:42</p> <p>20 Did you look at the one that you received 10:42</p> <p>21 prior to coming on January 25th? 10:42</p> <p>22 A. For today? 10:43</p> <p>23 Q. No, before you came on January 25th. 10:43</p> <p>24 A. Yes. 10:43</p> <p>25 Q. And did you review that notice to 10:43</p>

27 (Pages 102 to 105)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 106			Page 108		
1	identify documents and other materials that you	10:43	1	behalf.	10:45
2	were supposed to bring with you on January 25th?	10:43	2	A. Uh-huh.	10:45
3	A. For the 25th one?	10:43	3	Q. And attorneys representing the	10:45
4	Q. Yes.	10:43	4	Plaintiffs in this litigation.	10:45
5	A. Yeah.	10:43	5	A. Uh-huh.	10:45
6	Q. One second, getting a drink.	10:43	6	Q. Do you understand that request?	10:45
7	A. May I do the same?	10:43	7	A. Yes.	10:45
8	Q. Uh-huh, yes you may. Yes, you may.	10:43	8	Q. Did you bring those materials with you?	10:45
9	We'll stay on the record.	10:43	9	Do you have all correspondence and communication	10:45
10	Are you ready?	10:43	10	between yourself or your wife as a --	10:45
11	A. Yes, sir.	10:44	11	A. Uh-huh.	10:45
12	Q. So Dr. Bliesner, you did not receive any	10:44	12	Q. -- representative of Delphi?	10:45
13	notice of today's deposition?	10:44	13	A. Uh-huh.	10:45
14	A. Not that I recall, no.	10:44	14	Q. Or -- these invoices are under Delphi.	10:45
15	Q. Before you came on January 25th --	10:44	15	Do you have all correspondence between you, your	10:45
16	A. Uh-huh.	10:44	16	wife, or anyone at Delphi and any of the	10:45
17	Q. -- to the first session of your	10:44	17	Plaintiffs' lawyers with you today?	10:45
18	deposition, did you review the notice that you	10:44	18	A. The original e-mails were copied off the	10:45
19	received for the 25th and collect all of the	10:44	19	hard drive and Miss Johnson has them. So to	10:46
20	information, documents, and materials that were	10:44	20	answer your question, that set of e-mails I do not	10:46
21	identified in the notice to bring with you?	10:44	21	have with me. It's not on the hard drive.	10:46
22	A. I did.	10:44	22	Q. Not on the hard drive?	10:46
23	Q. And did you bring them with you on that	10:44	23	A. I have e-mails since that time that the	10:46
24	day?	10:44	24	communications are on that hard drive.	10:46
25	A. I did.	10:44	25	Q. So the original e-mails were copied off	10:46

Page 107			Page 109		
1	Q. Did you bring them with you again today?	10:44	1	of that same hard drive that you brought with you	10:46
2	A. I did.	10:44	2	today?	10:46
3	Q. Same materials?	10:44	3	A. Yes, sir.	10:46
4	A. Yes.	10:44	4	Q. Given -- printed off of that?	10:46
5	Q. Is there anything that you brought with	10:44	5	A. No, they were just copied as file.	10:46
6	you on the 25th that isn't here today?	10:44	6	Q. When did that happen?	10:46
7	A. No.	10:44	7	A. The 24th, I believe. That was the day	10:46
8	Q. You went through and organized them per	10:44	8	before.	10:46
9	the --	10:44	9	Q. So you brought them on that same hard	10:46
10	A. Uh-huh.	10:44	10	drive on January 24th to your meeting with	10:46
11	Q. -- suggestion of Mr. Kerensky?	10:44	11	Plaintiffs' counsel?	10:46
12	A. Uh-huh.	10:44	12	A. Yes.	10:46
13	Q. But you brought the same materials with	10:44	13	Q. And in that meeting, somebody copied	10:46
14	you?	10:44	14	them off of that hard drive onto some media that	10:46
15	A. Uh-huh.	10:44	15	they brought with them?	10:46
16	Q. I'll represent to you, Dr. Bliesner,	10:44	16	A. Yes.	10:46
17	that this notice is identical to the prior notice	10:44	17	Q. Who was that?	10:46
18	except for the date and time. Mr. Kerensky will	10:44	18	A. It was Miss Johnson.	10:46
19	speak up and tell me if I'm wrong. But item	10:45	19	Q. What was the media she copied it onto,	10:46
20	number 2 --	10:45	20	do you know?	10:46
21	A. Uh-huh.	10:45	21	A. I don't recall.	10:46
22	Q. -- requests that you bring all	10:45	22	Q. And then after that meeting --	10:46
23	correspondence and communication between the	10:45	23	A. Uh-huh.	10:47
24	witness -- that's you -- and anyone acting on the	10:45	24	Q. -- did you bring that -- did you have	10:47
25	witness's behalf. So anyone acting on your	10:45	25	that hard drive with you on the 25th?	10:47

28 (Pages 106 to 109)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 110			Page 112		
1	A. Yes.	10:47	1	computer, and she goes -- there's e-mail and	10:48
2	Q. Were the e-mails between you and	10:47	2	communications back and forth here. You got to	10:48
3	Plaintiffs' counsel still on the hard drive at	10:47	3	figure out -- words to this effect, you know -- a	10:48
4	that time?	10:47	4	good way to distribute them so we're not passing	10:48
5	A. No.	10:47	5	the hard drive around. She goes so I'm going to	10:48
6	Q. So you went home on the 24th and you	10:47	6	cut them off and then I'll make sure they're	10:48
7	removed them?	10:47	7	available to people.	10:49
8	A. No, no. She copied them off.	10:47	8	Q. Okay. She removed them from your hard	10:49
9	Q. Well, when you copy, you don't remove.	10:47	9	drive.	10:49
10	A. She removed them. She copied -- cut the	10:47	10	A. Yes.	10:49
11	whole folder and dropped it over onto her	10:47	11	Q. And you don't have them here today.	10:49
12	computer.	10:47	12	A. No. You have e-mails since that time of	10:49
13	Q. So you had that hard drive with you on	10:47	13	communication.	10:49
14	the 25th but you didn't have the e-mails with you.	10:47	14	Q. On this hard drive.	10:49
15	A. No, she he did.	10:47	15	A. Yes.	10:49
16	Q. She did?	10:47	16	Q. All e-mails, all correspondence between	10:49
17	A. Yeah.	10:47	17	you and Plaintiffs' counsel?	10:49
18	MR. ANDERTON: You see that we have a	10:47	18	A. There should be, yes. I'm pretty	10:49
19	problem here, Mr. Kerensky? Mike?	10:47	19	meticulous about when I get that, I make sure it	10:49
20	MR. KERENSKY: Sorry, I was on mute. I	10:47	20	goes onto the hard drive.	10:49
21	don't think -- I'm pretty sure Meghan sent	10:47	21	Q. So you're pretty meticulous that you	10:49
22	those to me and I was supposed to bring them.	10:47	22	preserve and maintain a complete set of records?	10:49
23	I am looking for an e-mail. Why don't you	10:47	23	A. Yes.	10:49
24	move to another subject and I'll see if I can	10:47	24	Q. The documents that Mr. Miller and Ms	10:49
25	solve it in a minute.	10:47	25	Johnson delivered in person to you at your home,	10:49
Page 111			Page 113		
1	BY MR. ANDERTON:	10:47	1	what were they?	10:49
2	Q. Okay. So back to -- well, I'm going to	10:48	2	A. I could show you.	10:49
3	stay on this subject for a minute. She copied	10:48	3	Q. Please do.	10:50
4	them onto some media that she had.	10:48	4	A. We're talking just about that visit at	10:50
5	A. Yeah, I believe it was her computer.	10:48	5	the home office.	10:50
6	Q. Okay.	10:48	6	Q. Well, were there other visits where they	10:50
7	A. That she was going to share with	10:48	7	delivered documents to you?	10:50
8	everybody.	10:48	8	A. No.	10:50
9	Q. And then you removed them from your hard	10:48	9	Q. Just one?	10:50
10	drive?	10:48	10	A. Yes.	10:50
11	A. No, no, no. She took them off.	10:48	11	Q. Okay. Is that it?	10:50
12	Everything that I've done with respect to	10:48	12	A. The first set, they did not deliver. I	10:51
13	electronic records and everything else,	10:48	13	apologize for that.	10:51
14	communication, has been on that external hard	10:48	14	Q. The first set?	10:51
15	drive.	10:48	15	A. That's stuff I had mailed to me	10:51
16	Q. This one you brought you?	10:48	16	originally.	10:51
17	A. This exact reason. It could be shared	10:48	17	Q. Okay.	10:51
18	with people.	10:48	18	A. So on that particular day, it would have	10:51
19	Q. Okay.	10:48	19	been the second set I'm pretty sure.	10:51
20	A. So when we met on the 24th.	10:48	20	Q. These two binders labeled second set?	10:51
21	Q. Correct.	10:48	21	A. Yeah. There may have been some	10:51
22	A. Right? They said so do you have any	10:48	22	additional documents mailed to me prior to that	10:51
23	e-mails? And I said yeah, I did what you told.	10:48	23	day, but they're all in here.	10:51
24	Here they are on the external hard drive and Miss	10:48	24	Q. All right. You can sit back down.	10:52
25	Johnson plugged it in I believe it was her	10:48	25	A. Sure.	10:52

29 (Pages 110 to 113)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 114			Page 116		
1	Q. That's all right.	10:52	1	A. Right, right.	10:54
2	A. Uh-huh.	10:52	2	Q. That's the military background; right?	10:54
3	Q. The other documents -- well, are there	10:52	3	A. Or just anal retentiveness as a human	10:54
4	other documents that you have received from	10:52	4	being.	10:54
5	Plaintiffs' counsel as part of your engagement?	10:52	5	Q. Okay.	10:54
6	A. I've reviewed through this Crivella West	10:52	6	A. The reason I'm not saying absolutely	10:54
7	site.	10:52	7	yes, this is it, is that I'd have to go back and	10:54
8	Q. Okay.	10:52	8	look at the electronic records to make sure that	10:54
9	A. Some of which I printed out to review,	10:52	9	there was one attached that I didn't review or I	10:54
10	others which I just left online because they were	10:52	10	forgot about that would be there.	10:54
11	too big.	10:52	11	Q. But those would be included among e-mail	10:54
12	Q. Okay. Are these the only documents that	10:52	12	communications?	10:54
13	you've actually received from Plaintiffs' counsel?	10:52	13	A. Yes.	10:54
14	A. No.	10:52	14	Q. That Miss Johnson --	10:54
15	Q. What else have you received from	10:53	15	A. Yes.	10:54
16	Plaintiffs' counsel?	10:53	16	Q. -- took from you and hasn't produced to	10:54
17	A. Yesterday evening, late, I believe I got	10:53	17	us.	10:54
18	one or two reports from process development or	10:53	18	A. If she hasn't produced them, yes.	10:54
19	something like that. I didn't review them.	10:53	19	Q. Okay. Are there any other documents at	10:54
20	Q. Process validation?	10:53	20	your home that you did not bring with you today	10:54
21	A. I'm trying -- I don't recall because I	10:53	21	that you have received from Plaintiffs' counsel?	10:54
22	didn't look at them.	10:53	22	A. No.	10:54
23	Q. Okay.	10:53	23	MR. ANDERTON: Phil, we're going to mark	10:54
24	A. I got a document. I know that and I	10:53	24	these. There are four of them. We're marking	10:54
25	just didn't look at it.	10:53	25	documents Mike. Just show you know, there's a	10:55
Page 115			Page 117		
1	Q. Who did you get that from?	10:53	1	stack and three binders. We'll make	10:55
2	A. Miss Johnson.	10:53	2	arrangements to get them copied and back to	10:55
3	Q. Yesterday?	10:53	3	Dr. Bliesner.	10:55
4	A. Evening, yes.	10:53	4	MR. KERENSKY: No problem. Who is going	10:55
5	Q. Mail? Electronic? How did you get it?	10:53	5	to do the copying?	10:55
6	A. It was electronic.	10:53	6	MR. ANDERTON: We will figure that out	10:55
7	Q. By e-mail?	10:53	7	before we leave today.	10:55
8	A. Yes.	10:53	8	MR. KERENSKY: Very good.	10:55
9	Q. Is the e-mail --	10:53	9	THE WITNESS: Now, there are an	10:55
10	A. Should be on there, yes.	10:53	10	additional documents that support the report,	10:55
11	Q. Is that on the hard drive?	10:53	11	the attachments.	10:55
12	A. Yeah, should be there.	10:53	12	(Whereupon, Exhibits 147, 148, 149,	10:55
13	Q. The -- other than the documents you	10:53	13	150 were marked for identification)	10:55
14	received yesterday electronically from	10:53	14	BY MR. ANDERTON:	10:55
15	Ms. Johnson, are there any other documents in	10:53	15	Q. Uh-huh.	10:55
16	addition to the ones that you've handed me today	10:53	16	A. Do you want those as well?	10:55
17	that you actually received from Plaintiffs'	10:53	17	Q. Well, we'll get there.	10:55
18	counsel?	10:53	18	A. Okay.	10:55
19	A. Not that I recall. I think this is	10:53	19	Q. I take it those are documents that you	10:55
20	pretty much it, yeah. It's a lot of stuff so to	10:53	20	reviewed and printed from the Crivella West?	10:55
21	say definitively everything I've got is here.	10:53	21	A. They could have been provided at some	10:55
22	Q. You just said you're a pretty meticulous	10:54	22	point through this document delivery that you've	10:56
23	--	10:54	23	talked about. They e-mailed me some, they mailed	10:56
24	A. Right.	10:54	24	me some, and then they delivered some personally.	10:56
25	Q. -- detailed guy.	10:54	25	So they're all weaved together.	10:56

30 (Pages 114 to 117)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 118			Page 120		
1	Q. But I asked you, Dr. Bliesner, if there	10:56	1	question, it appears to be that and some more.	10:59
2	are any other documents that you've received from	10:56	2	Q. Okay. But you received those prior	10:59
3	Plaintiffs' counsel. I didn't specify personal	10:56	3	to -- somewhat close in proximity to the last	10:59
4	delivery.	10:56	4	deposition session.	10:59
5	A. Well.	10:56	5	A. Yeah.	10:59
6	Q. That's what you gave me when you gave me	10:56	6	Q. As I look at these binders that have	10:59
7	these things.	10:56	7	been marked as 148, 149 and 150.	10:59
8	A. I'm sorry. I misunderstood you because	10:56	8	A. Uh-huh.	10:59
9	I thought you said just for that visit at the home	10:56	9	Q. I see highlighting on various	10:59
10	office. I'm sorry.	10:56	10	documents. Who did the highlighting?	10:59
11	Q. Okay.	10:56	11	A. Let's see.	10:59
12	A. Uh-huh.	10:56	12	Q. In particular, I'm looking at --	10:59
13	Q. So let's make sure.	10:56	13	A. Oh.	10:59
14	A. Okay.	10:56	14	Q. -- the third set of supplemental	10:59
15	Q. It's imperative --	10:56	15	documents.	10:59
16	A. Uh-huh.	10:56	16	Who did the highlighting?	10:59
17	Q. -- Dr. Bliesner that you listen very	10:56	17	A. Me.	10:59
18	carefully to the questions that I ask.	10:56	18	Q. Is it true that any highlighting that I	10:59
19	A. I understand.	10:56	19	will encounter on these documents was done by you?	10:59
20	Q. Are there any other documents that you	10:56	20	A. I believe so, yes.	10:59
21	have received from Plaintiffs' counsel --	10:56	21	Q. Okay.	10:59
22	A. Uh-huh, yes. Sorry.	10:56	22	A. I -- nobody pointed out anything	10:59
23	Q. -- that you have with you today?	10:56	23	specifically for me to...	11:00
24	A. Yes.	10:56	24	Q. You can have that stack back and you can	11:00
25	Q. We're going to mark them. You've handed	10:56	25	put it away.	11:00
Page 119			Page 121		
1	me two more binders.	10:57	1	A. Okay.	11:00
2	A. Yes, sir.	10:57	2	Q. We're not going to copy that or mark	11:00
3	Q. They have post-it notes on the key	10:57	3	it.	11:00
4	documents A1 to A30 and A31 to A63?	10:57	4	A. Okay.	11:00
5	A. Yes, sir.	10:57	5	Q. Now, you've handed me another binder of	11:00
6	Q. Who designated them key documents?	10:57	6	deposition transcripts.	11:00
7	A. Me.	10:57	7	A. Yeah. Those were printed out off of	11:00
8	Q. Okay. I've got another stack of	10:57	8	Crivella.	11:00
9	documents with a post it on it that says last	10:58	9	Q. You can have that back. We're not going	11:00
10	supplemental set; right?	10:58	10	to mark that.	11:00
11	A. Yes.	10:58	11	A. Okay.	11:00
12	Q. What is that?	10:58	12	Q. Are there any other documents,	11:00
13	A. Those were -- if I recall those were	10:58	13	Dr. Bliesner, that you have received from	11:01
14	printouts of e-mails that I received from one of	10:58	14	Plaintiffs' counsel that you brought with you	11:01
15	the attorneys prior to the 25th.	10:58	15	today?	11:01
16	Q. Okay.	10:58	16	A. Other than the electronic ones that I	11:01
17	A. I believe that we reviewed those. You	10:58	17	could not account for, not to my knowledge, no.	11:01
18	have them as well and we've reviewed them.	10:58	18	Q. Okay.	11:01
19	Q. Okay.	10:58	19	A. Uh-huh.	11:01
20	A. Uh-huh.	10:58	20	Q. What else is in the boxes that you	11:01
21	Q. So these appear to be all or largely the	10:58	21	brought with you today?	11:01
22	records relating to the FDA 484 sampling program.	10:58	22	A. Today?	11:01
23	You can stay right there.	10:58	23	Q. Just describe it.	11:01
24	A. Okay. It looks like there's an	10:58	24	A. Describe it? Textbook, the transcript	11:01
25	additional set there too. So to answer your	10:59	25	of the last deposition that I need to review.	11:01

31 (Pages 118 to 121)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 122			Page 124		
1	Q. What else?	11:01	1	A. Yes.	11:15
2	A. I think I've got some notes from -- the	11:01	2	Q. Do you remember that?	11:15
3	stuff like this.	11:01	3	A. Yes, uh-huh.	11:15
4	Q. Some notes like that or --	11:01	4	Q. You described those as your handwritten	11:16
5	A. Would you like me to look?	11:01	5	notes. Did you take two sets of notes that day?	11:16
6	Q. Sure.	11:01	6	A. I cleaned them up so I could read them.	11:16
7	A. Because I'm not sure whether you have	11:01	7	Q. When did you do that?	11:16
8	copies of this or not.	11:01	8	A. I don't recall, but I think it was at	11:16
9	Q. Well, let me see the notes.	11:01	9	the same time, like at the end of the day.	11:16
10	A. Sure. That's it. Did you want to --	11:01	10	Q. Okay. So the document that is 109, is	11:16
11	Q. No.	11:01	11	that the uncleaned up version or is it the cleaned	11:16
12	A. Okay.	11:01	12	up version?	11:16
13	MR. ANDERTON: While -- Phil, while we're	11:02	13	A. This one right here?	11:16
14	at it, we may as well mark the notice. Mike,	11:02	14	Q. 109.	11:16
15	I'm marking the notice as 151.	11:02	15	A. Yeah, I think that's just the summary at	11:16
16	(Whereupon, Exhibit 151 was marked	11:02	16	the end of the -- this and the other notes that	11:16
17	for identification)	11:02	17	were there.	11:16
18	BY MR. ANDERTON:	11:02	18	Q. So the document that's 152 --	11:16
19	Q. Do you have any other notes with you?	11:02	19	A. Uh-huh.	11:16
20	A. No.	11:02	20	Q. -- let's get them both in front you.	11:16
21	Q. Okay. You described -- you said you had	11:02	21	A. Okay.	11:16
22	your textbook, you said you had your deposition	11:02	22	Q. I'm also handling you a document that is	11:16
23	transcript, you said you had these additional	11:03	23	marked 153.	11:16
24	notes that we're about to mark.	11:03	24	A. Uh-huh.	11:16
25	A. Uh-huh.	11:03	25	Q. What is that?	11:16

Page 123			Page 125		
1	Q. Do you have anything else with you in	11:03	1	A. 153 looks like notes from a conversation	11:16
2	the boxes that you brought today?	11:03	2	I had.	11:16
3	A. No.	11:03	3	Q. With?	11:16
4	MR. ANDERTON: Phil, would you mark these	11:03	4	A. It looks like -- specifically, I'm not	11:16
5	as 152 and 3? Mike, these are additional sets	11:03	5	sure who called me. It was either Pete or Meghan	11:17
6	of notes.	11:03	6	to tell me a time.	11:17
7	(Whereupon, Exhibits 152 and 153	11:03	7	Q. To tell you a time?	11:17
8	were marked for identification)	11:03	8	A. Yeah, hold on. That's not right. 10 --	11:17
9	THE VIDEOGRAPHER: The time is	11:03	9	oh, I'd have to look at the calendar. We did our	11:17
10	a.m. We're going off the record.	11:03	10	deposition on what day of the week?	11:17
11	(Short break)	11:14	11	Q. Tuesday.	11:17
12	THE VIDEOGRAPHER: The time is	11:14	12	A. Tuesday, yes. So this was notes with	11:17
13	11:14 a.m. We're back on the record. This is	11:15	13	respect to them, to meet me on the Monday before.	11:17
14	the beginning of tape four.	11:15	14	Q. And by "this," you mean Exhibit 153?	11:17
15	BY MR. ANDERTON:	11:15	15	A. Yes.	11:17
16	Q. Dr. Bliesner, I'm going to hand you a	11:15	16	Q. But this is notes of a phone	11:17
17	document that has been marked as Exhibit 152.	11:15	17	conversation that obviously occurred before Monday	11:17
18	A. Yes.	11:15	18	24th; right?	11:17
19	Q. Tell me what that is.	11:15	19	A. I suppose that's -- that's the case,	11:17
20	A. That's my handwritten notes I believe it	11:15	20	yes.	11:17
21	was for the day when I met before the first	11:15	21	Q. You suppose?	11:17
22	deposition with the attorneys.	11:15	22	A. It doesn't have a date on it. I don't	11:17
23	Q. Your handwritten notes. Okay. Well, we	11:15	23	have a time so I can't tell you definitively what	11:17
24	had some testimony earlier about a document that's	11:15	24	day.	11:17
25	marked as 109.	11:15	25	Q. Are these notes that you took during	11:17

32 (Pages 122 to 125)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 126			Page 128		
1	that meeting with the lawyers?	11:18	1	interpreted it, it's -- that's not an accurate	11:19
2	A. No.	11:18	2	statement. It's just notes that I had. I just	11:19
3	Q. And it references a meeting time and	11:18	3	gave you my notes. Now what days they were on	11:19
4	place, 10 a.m., 10, Monday, 100 North Tampa.	11:18	4	specifically, that's what we're trying to	11:19
5	A. Right. So chances are it's the	11:18	5	determine right now.	11:20
6	telephone record.	11:18	6	Q. And you're unable to do that.	11:20
7	Q. You mean record of notes during a	11:18	7	A. Considering I didn't put a date at the	11:20
8	telephone conversation?	11:18	8	top, yeah.	11:20
9	A. When they called up and said, you know,	11:18	9	Q. So let's look at Exhibit 152 --	11:20
10	we want to get together on the 24th, the day	11:18	10	A. Okay.	11:20
11	before.	11:18	11	Q. -- first; okay?	11:20
12	Q. Well, this is a lot more than we want to	11:18	12	A. Okay.	11:20
13	get together on 24th, isn't it, Dr. Bliesner?	11:18	13	Q. The top says "90 percent." What does	11:20
14	A. This sheet is. The rest of them, I'm	11:18	14	that mean?	11:21
15	not sure where -- if that was part of the day	11:18	15	A. I'm not really sure. I'm thinking that	11:21
16	that -- on the day before the deposition or not.	11:18	16	it was a reference to listening to the question	11:21
17	I -- I really -- because I don't have a date and a	11:18	17	like you've said and thinking about what's really	11:21
18	time on it here. Just -- I think that this --	11:18	18	been said as opposed to jumping in and trying to	11:21
19	this page 2 here of 153.	11:18	19	answer without really understanding the question.	11:21
20	Q. Yeah.	11:18	20	So 90 percent of the effort would be sitting down,	11:21
21	A. If I had to offer a suggestion, I think	11:18	21	listening to the question, and making sure that	11:21
22	that those pages probably went with this, the	11:18	22	you're answering in a way that's accurate.	11:21
23	preparation day.	11:19	23	Q. Under there it says, "defending turf."	11:21
24	Q. So you think these are notes that you	11:19	24	What does that mean?	11:21
25	made when you met with them on the 24th?	11:19	25	A. I believe that was guidance, since I	11:21
Page 127			Page 129		
1	A. Yes.	11:19	1	have never done this before, that, you know, don't	11:21
2	Q. And you think 152 are notes that you	11:19	2	allow yourself to be headed down a direction that	11:22
3	made when you met with them on the 24th?	11:19	3	isn't the truth. So, again, I as said before,	11:22
4	A. 152.	11:19	4	this is such -- so different than the	11:22
5	Q. Yes.	11:19	5	collaborative stuff that -- that I've done in the	11:22
6	A. Yes.	11:19	6	past that obviously I need a little instruction on	11:22
7	Q. And you think that 109 is a clean up of	11:19	7	how to do this.	11:22
8	notes you made when you met with them on the 24th	11:19	8	Q. Well, it would be great if this was	11:22
9	and made them later that day?	11:19	9	collaborative. You're obviously getting guidance	11:22
10	A. Yes.	11:19	10	on how to make it combative; right?	11:22
11	Q. Three sets of notes, Dr. Bliesner.	11:19	11	MR. KERENSKY: Objection, form.	11:22
12	Really?	11:19	12	BY MR. ANDERTON:	11:22
13	A. Three set pages.	11:19	13	Q. You may answer.	11:22
14	Q. In the same day?	11:19	14	A. Could you say the question again?	11:22
15	A. This is the telephone conversation.	11:19	15	MR. ANDERTON: Read it back, please,	11:22
16	Q. The first page of Exhibit 153.	11:19	16	Phil.	11:22
17	A. 153.	11:19	17	(Whereupon, the testimony was read	11:22
18	Q. Your testimony is that what remains in	11:19	18	back by the court reporter, as recorded above)	11:22
19	153 -- and just so we're clear --	11:19	19	THE WITNESS: I wouldn't agree with that.	11:22
20	A. Uh-huh.	11:19	20	BY MR. ANDERTON:	11:22
21	Q. -- you handed me the document that we've	11:19	21	Q. You don't think that somebody telling	11:22
22	marked as Exhibit 153 --	11:19	22	you to defend your turf isn't a guidance on how to	11:22
23	A. Yes.	11:19	23	make a process combative?	11:22
24	Q. -- as a single group of notes; right?	11:19	24	A. Absolutely not.	11:22
25	A. I -- if that's how it's -- you	11:19	25	Q. Okay. In the next line there's a	11:22

33 (Pages 126 to 129)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 130		Page 132			
1	bracketed phrase that says "easier said than done." Is that what it says?	11:23	1	practices?	11:25
2	A. Where are we at again?	11:23	2	A. Yes.	11:25
3	Q. The first page of Exhibit 152, top of the page.	11:23	3	Q. Who created that list?	11:25
4	A. Easier said than done, yes.	11:23	4	A. Me.	11:25
5	Q. What does that mean?	11:23	5	Q. In the moment in that meeting with Plaintiffs' lawyers?	11:25
6	A. To listen very carefully, things are in the box. To listen to the questions. Don't guess or propose a hypothesis and then the third and fourth thing. So that's what it is. It's very simple guidance, but it's, as I'm discovering, not real easy.	11:23	6	A. Yeah.	11:25
7	Q. What do you mean by that?	11:23	7	Q. Did they make suggestions on -- as to what ought to be on the list?	11:25
8	A. It's just hard work.	11:23	8	A. Not really.	11:25
9	Q. I think you're making it harder than it actually is, Dr. Bliesner, but that's just my humble opinion.	11:23	9	Q. Batch records isn't on that list, is it?	11:25
10	The next page of Exhibit 152 says "write these down."	11:24	10	A. Specifically, no.	11:25
11	A. Uh-huh.	11:24	11	Q. "The big yes but tell me everything." That notation can be seen on this page 2 of the Exhibit 152; is that right?	11:25
12	Q. Why did you make that note?	11:24	12	A. Yes.	11:25
13	A. I believe the conversation went to this effect, you know? How do you -- in your report, what are the things that come to mind off the top	11:24	13	Q. What does that mean?	11:25
14			14	A. To tell you the truth, I have no idea.	11:25
15			15	Q. Your notes.	11:25
16			16	A. I know it's my notes, but I have no idea what that means. I really don't.	11:25
17			17	Q. What does the bottom note say "and that's dangerous"?	11:25
18			18	A. Yeah.	11:26
19			19	Q. What does that mean?	11:26
20			20		
21			21		
22			22		
23			23		
24			24		
25			25		

Page 131		Page 133			
1	of your head that line up in some entry position outside of the report. So I went (witness makes noise) right off the top of my head.	11:24	1	A. To tell you the truth, I don't remember in this conversation.	11:26
2	Q. So in essence what are the documents that support the conclusions in your report?	11:24	2	Q. Let's go look at Exhibit 153.	11:26
3	A. Yeah.	11:24	3	A. Okay.	11:26
4	Q. And so they are the AERs, adverse event reports; right?	11:24	4	Q. And let's look at the second page of Exhibit 153.	11:26
5	A. Uh-huh.	11:24	5	A. Okay.	11:26
6	Q. The FDA documents; right?	11:24	6	Q. What is that list of six things?	11:26
7	A. Yes.	11:24	7	A. Looks like references to documents that are included in the report.	11:26
8	Q. Pharmacy complaints; right?	11:24	8	Q. Who made the list?	11:26
9	A. Yes.	11:24	9	A. Well, I wrote the list.	11:26
10	Q. Deposition testimony?	11:24	10	Q. Why? What's the intention of making the list?	11:26
11	A. Yes.	11:24	11	A. I'm trying to -- trying to remember.	11:26
12	Q. Company responses to FDA inspections?	11:24	12	Q. Please do.	11:26
13	A. Yes.	11:25	13	A. Uh-huh. As we said before I'm pretty sure these are pages that went with the -- this set, the notes. I'm not sure when these notes were made, if it was with this or if it was this conversation because I don't have a time and a date on it, but it was some suggestions that if I wanted to -- in preparation for the deposition that the -- I go back and look at them since they were in my report -- by one of the attorneys.	11:26
14	Q. Company internal document/investigations?	11:25	14		11:27
15	A. Yes.	11:25	15		11:27
16	Q. Recall documents?	11:25	16		11:27
17	A. Yes.	11:25	17		11:27
18	Q. Mylan documents?	11:25	18		11:28
19	A. Yes.	11:25	19		11:28
20	Q. Deviation from standard industry	11:25	20		11:28
21			21		
22			22		
23			23		
24			24		
25			25		

34 (Pages 130 to 133)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 134			Page 136		
1	Q. So one of the attorneys -- the list on	11:28	1	Q. The consequences indifferent for the --	11:30
2	the second page of Exhibit 153 is a list of	11:28	2	what's that word after "the"?	11:30
3	suggestions made by one of the lawyers for the	11:28	3	A. I don't know.	11:30
4	Plaintiffs on things that you should go review	11:28	4	Q. For the health, perhaps?	11:30
5	prior to your deposition?	11:28	5	A. I don't know.	11:30
6	A. As I recall, yeah, they were	11:28	6	Q. And welfare of the person involved?	11:30
7	suggestions. Just if I wanted to go back and look	11:28	7	A. I -- I can't tell you.	11:30
8	at it, yeah, I could, so...	11:28	8	Q. You can't read your own writing?	11:30
9	Q. And somebody advised you to look for	11:28	9	A. No, I can't.	11:30
10	specific failures which resulted in blend	11:28	10	Q. One of the lawyers --	11:30
11	uniformity; right?	11:28	11	A. It was a term that came up and I go	11:30
12	A. No, I already had. They were just	11:28	12	what's that? I never heard it before. So I just	11:30
13	saying, you know, if I wanted to go back and	11:28	13	jotted it down.	11:30
14	review it, that they would suggest that.	11:28	14	Q. Did they tell you to work it into one of	11:30
15	Q. To look for specific failures which	11:28	15	your answers?	11:30
16	resulted in blend uniformity?	11:28	16	A. No.	11:30
17	A. Right, which is in the report.	11:28	17	Q. Did they tell you that it's a topic and	11:30
18	Q. What does that mean "look for specific	11:28	18	a concept you should be familiar with as you	11:30
19	failures which resulted in blend uniformity"?	11:28	19	responded to questions?	11:31
20	What I've just read is a quote from your notes.	11:28	20	A. Gross negligence?	11:31
21	What does it mean?	11:28	21	Q. Yes.	11:31
22	A. It's not a quote. It's just my notes.	11:29	22	A. No.	11:31
23	Q. I've read it.	11:29	23	Q. Did you use that term in your report	11:31
24	A. I don't recall specifically what the	11:29	24	ever?	11:31
25	guidance was on that. They made suggestions. If	11:29	25	A. I would have to go back and review it.	11:31

Page 135			Page 137		
1	I want to review the documents, I did. I can tell	11:29	1	I don't think so.	11:31
2	you this: Is that this list that is listed here	11:29	2	Q. Well, Dr. Bliesner --	11:31
3	it was suggestions. I didn't go back and review	11:29	3	A. Uh-huh. Because I've never heard it,	11:31
4	those documents. I just reviewed the report.	11:29	4	so...	11:31
5	Q. I see on the right side about halfway	11:29	5	Q. Dr. Bliesner, this is why this process	11:31
6	down that page.	11:29	6	takes so long.	11:31
7	A. Uh-huh.	11:29	7	A. Okay.	11:31
8	Q. An underlined term "gross negligence."	11:29	8	Q. You tell me you've never heard the term	11:31
9	Is that what it says?	11:29	9	before this meeting which would have occurred long	11:31
10	A. It is.	11:29	10	after your report was prepared.	11:31
11	Q. What does that mean?	11:29	11	A. Uh-huh.	11:31
12	A. Apparently that's a definition that one	11:29	12	Q. Do you really have to go back and look	11:31
13	of the attorneys gave me because I'd never heard	11:29	13	at your report to tell me whether that term is in	11:31
14	the term before. Somebody was talking about it	11:29	14	your report if you had never heard it before? Now	11:31
15	and I go what's that? So I jotted it down. Never	11:29	15	I understand that you prepared and were told to be	11:31
16	heard it before.	11:29	16	cautious in answering questions, but this process	11:31
17	Q. Which attorney?	11:29	17	takes as long as it does because of your	11:31
18	A. I don't know.	11:29	18	deliberately being difficult like that.	11:31
19	Q. What does it say underneath it. I can't	11:29	19	MR. KERENSKY: We don't need this kind of	11:31
20	read that. Can you please read that for me?	11:29	20	speech, Mike.	11:31
21	A. I think it's supposed to be consequences	11:30	21	MR. ANDERTON: What I need, Mike, is a	11:31
22	indifferent from -- I don't know those three	11:30	22	witness who will answer the questions that are	11:31
23	words. And welfare of persons involved in the	11:30	23	put to him.	11:31
24	action with involved risk, suicide, injury, or	11:30	24	MR. KERENSKY: Well, I think he's doing a	11:31
25	death. I just jotted it down quickly.	11:30	25	great job of that. And we don't need your	11:32

35 (Pages 134 to 137)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 138			Page 140		
1	speech. And really this is out of bounds.	11:32	1	mean?	11:34
2	You ask all questions you want, but making	11:32	2	A. That was the list that I came up with	11:34
3	speeches like this is highly objectionable.	11:32	3	off the top of my head.	11:34
4	You're just trying to intimidate the witness,	11:32	4	Q. The next page of that same Exhibit 153	11:34
5	which will not work.	11:32	5	is note that says, "are you aware of the fact that	11:34
6	MR. ANDERTON: I'm not trying to --	11:32	6	FDA" and then a semi-colon. What does that mean?	11:34
7	MR. KERENSKY: He's not intimidated and	11:32	7	A. I have no idea.	11:34
8	neither am I.	11:32	8	Q. The next item, number two, says	11:34
9	MR. ANDERTON: I'm not trying to --	11:32	9	"possible equals we loose." I assume that you	11:34
10	MR. KERENSKY: So why don't you just ask	11:32	10	meant to say "we lose."	11:34
11	questions.	11:32	11	A. I believe that's what it was intended to	11:34
12	MR. ANDERTON: Are you done, Mike?	11:32	12	be.	11:34
13	MR. KERENSKY: I'm done.	11:32	13	Q. So "loose" is a misspelling of "lose"?	11:34
14	MR. ANDERTON: I'm not trying to	11:32	14	A. I would assume that's correct, yes.	11:34
15	intimidate anyone. I'm merely trying to get	11:32	15	Q. "Possible equals we lose." What does	11:34
16	this process to move forward. What we're	11:32	16	that mean?	11:35
17	going to see as we make our way through these	11:32	17	A. I believe it was one of the attorneys	11:35
18	notes is that Dr. Bliesner is holding very	11:32	18	talking about trying to define for me "possible"	11:35
19	firmly to certain concepts he was -- that were	11:32	19	and "probable" because I didn't understand it.	11:35
20	given to him by the lawyers in this case and	11:32	20	Q. So you then -- well, so you discussed	11:35
21	is deliberately being non-responsive.	11:32	21	with Plaintiffs' counsel the difference between	11:35
22	MR. KERENSKY: That's a total	11:32	22	"possible" and "probable," right?	11:35
23	mischaracterization of what's going on here.	11:32	23	A. Yes.	11:35
24	BY MR. ANDERTON:	11:32	24	Q. And you didn't understand it before that	11:35
25	Q. Dr. Bliesner, does the term gross	11:32	25	conversation; right?	11:35
Page 139			Page 141		
1	negligence appear in your report?	11:32	1	A. That's correct. In legal terms.	11:35
2	A. Not that I recall.	11:32	2	Q. Did you understand it after that	11:35
3	Q. The next page of Exhibit 153.	11:33	3	conversation?	11:35
4	A. Okay.	11:33	4	A. I still think I had difficulty with it	11:35
5	Q. Among other things is that same list	11:33	5	up until the deposition because Mr. -- what was	11:35
6	that we saw in Exhibit -- well, yeah. This	11:33	6	the other gentleman's name? Moriarty?	11:35
7	appears to be the same or a similar list that we	11:33	7	Q. Yeah, Moriarty.	11:35
8	saw in Exhibit 152.	11:33	8	A. Yeah. We went back and forth on it so I	11:35
9	Do you see that?	11:33	9	was still a little bit cloudy at that stage of the	11:35
10	A. This down here at the bottom?	11:33	10	game.	11:36
11	Q. Yeah.	11:33	11	Q. Okay. A little bit cloudy? You said	11:36
12	A. No.	11:33	12	you had no idea.	11:36
13	Q. About the same list, isn't it?	11:33	13	A. No. Gross negligence.	11:36
14	A. Yeah, it looks like it. This would be a	11:33	14	Q. No. When you were being examined by	11:36
15	transcript of this that was more readable.	11:33	15	Mr. Moriarty, you said you had no notion of the	11:36
16	Q. Okay.	11:33	16	difference between probable and possible.	11:36
17	A. Uh-huh.	11:33	17	A. I don't recall being that definitive.	11:36
18	Q. On the middle of the right side of this	11:33	18	We could look it up in the transcript.	11:36
19	page it says, "my top list." What does that mean?	11:33	19	Q. Well, we can. The record will show what	11:36
20	A. I'm sorry. Where are we talking about?	11:34	20	it shows.	11:36
21	Q. The middle of that page. It's the third	11:34	21	A. Okay.	11:36
22	page of Exhibit 153.	11:34	22	Q. But what you're now saying is you	11:36
23	A. The third page?	11:34	23	actually discussed that distinction with	11:36
24	Q. Middle right side, about halfway down,	11:34	24	Plaintiffs' counsel the day before you were	11:36
25	right edge, it says "my top list." What does that	11:34	25	deposed.	11:36

36 (Pages 138 to 141)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 142			Page 144		
1	A. Yes.	11:36	1	that the cases would not stand up if it was	11:39
2	Q. And they did such a great job in that	11:36	2	possible or may.	11:39
3	discussion that you came to that deposition still	11:36	3	BY MR. ANDERTON:	11:39
4	having no idea.	11:36	4	Q. So if you -- so you were told by the	11:39
5	A. Apparently they didn't prepare me very	11:36	5	Plaintiffs' counsel that if you acknowledged	11:39
6	well, did they?	11:36	6	something was only possible, Plaintiffs would	11:39
7	MR. KERENSKY: Oh, sorry.	11:36	7	lose?	11:39
8	BY MR. ANDERTON:	11:36	8	A. The conversation as I recall in this	11:39
9	Q. Now back to the substance of this	11:36	9	discussion was I need to determine in my mind	11:39
10	comment. "Possible equals we lose." You've told	11:36	10	based on my report and the data that I looked at	11:39
11	me that that jars your recollection that you were	11:36	11	those three things.	11:40
12	discussing the difference between probability and	11:36	12	Q. I understand that.	11:40
13	possibility with Plaintiffs' counsel.	11:36	13	A. Yes.	11:40
14	Now tell me what that means.	11:36	14	Q. But you were told that if you answer a	11:40
15	A. Probable, according to my notes and as I	11:37	15	question and acknowledge something was possible,	11:40
16	understand it now, probable means there's a	11:37	16	Plaintiffs would lose; right?	11:40
17	reasonable degree of a certainty.	11:37	17	A. Yes.	11:40
18	Q. Dr. Bliesner?	11:37	18	Q. And if you answered a question and	11:40
19	A. Yes.	11:37	19	acknowledged that something -- if you said may?	11:40
20	Q. Pay attention to my question and answer	11:37	20	A. Yes.	11:40
21	my question or we're going to be here all day, and	11:37	21	Q. Instead of probable, Plaintiffs would	11:40
22	we're going to be back for a third session.	11:37	22	lose.	11:40
23	A. Okay.	11:37	23	A. Yes.	11:40
24	Q. Tell me what your note, "possible equals	11:37	24	Q. So you were told not to answer questions	11:40
25	we lose" means. I didn't ask you to define	11:37	25	as possible or may, if possible; right?	11:40
Page 143			Page 145		
1	probable versus possible. I ask you now for the	11:37	1	A. No, that's not true at all.	11:40
2	third time to tell me what your note means.	11:37	2	Q. It isn't?	11:40
3	A. I'm thinking about it because it was --	11:37	3	A. I was told specifically these are the	11:40
4	Q. Take as much time as you need to think	11:37	4	conditions that may lead to "lose," if you will;	11:40
5	about it, but answer that question.	11:37	5	all right? And that I needed to make sure where I	11:40
6	A. I will. Can I get some more water,	11:37	6	was comfortable with respect to my report on those	11:40
7	please?	11:37	7	definitions, and it was up to me.	11:40
8	Q. Yes, you may.	11:37	8	Q. And how does -- how does your comfort	11:40
9	A. Thank you.	11:37	9	with respect to your report factor into whether	11:40
10	MR. ANDERTON: Let's go off the record.	11:38	10	the Plaintiffs are going to lose or not? That's	11:40
11	THE VIDEOGRAPHER: The time is 11:37 a.m.	11:38	11	not something you considered in drafting your	11:40
12	We're going off the record.	11:38	12	report, is it?	11:40
13	(Short break)	11:38	13	A. Could you say that again, please? I'm	11:40
14	THE VIDEOGRAPHER: Time is ; we're	11:38	14	not being a pain. I'm just trying to.	11:40
15	back on the record.	11:38	15	MR. ANDERTON: Phil would be happy to	11:40
16	MR. ANDERTON: Phil, will you read that	11:39	16	read that back to you.	11:40
17	last question back, please?	11:39	17	(Whereupon, the testimony was read	11:40
18	(Whereupon, the testimony was read	11:39	18	back by the court reporter, as recorded above)	11:40
19	back by the court reporter, as recorded above)	11:39	19	THE WITNESS: No, not at all. I didn't	11:41
20	THE WITNESS: From what I recall in the	11:39	20	consider win or loss or anything. I reviewed	11:41
21	conversation, possible leaves room for doubt;	11:39	21	the data, I put together a report, I drew	11:41
22	probable does not. And "may" leaves doubt.	11:39	22	conclusions based on the documents that I had	11:41
23	So from protecting, what do they call them,	11:39	23	reviewed, and that was it.	11:41
24	the client, that from a legal opinion, they	11:39	24	BY MR. ANDERTON:	11:41
25	were trying to describe to me they thought	11:39	25	Q. And as you prepared for the deposition	11:41

37 (Pages 142 to 145)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

	Page 146		Page 148
1 and to be asked questions about the analysis and	11:41	1 A. The attorneys. They don't understand	11:43
2 conclusions reached, you were told to consider	11:41	2 some of the subtleties in the manufacturing arena.	11:43
3 whether Plaintiffs would lose.	11:41	3 Q. So your testimony is that on the day	11:43
4 A. They said words to the effect, if I	11:41	4 before your deposition, almost three years into	11:43
5 recall, be aware that if you use these words this	11:41	5 this litigation, you felt that the Plaintiffs'	11:44
6 is what it means from a legal term. Because	11:41	6 lawyers you were working with needed guidance on	11:44
7 apparently I didn't understand the difference	11:41	7 something as basic as whether something was	11:44
8 between probable and possible. That's what they	11:41	8 sub-potent or whether there was a blend uniformity	11:44
9 said.	11:41	9 issue?	11:44
10 Q. So you were told that if you said	11:41	10 A. I can't state to that fact. I know	11:44
11 possible rather than probable, it would mean	11:42	11 there were two new people in the room -- mike and	11:44
12 Plaintiffs would lose?	11:42	12 what was the other gentleman's name? -- and they	11:44
13 A. Potentially, yes. But I was not	11:42	13 asked me questions so I jotted them down.	11:44
14 directed to specifically use those words or not	11:42	14 Q. Well, Dr. Bliesner --	11:44
15 use those words. It was me.	11:42	15 A. Uh-huh.	11:44
16 Q. I understand. And were you also told if	11:42	16 Q. -- this is one of those situations where	11:44
17 you say "may" rather than "probable," Plaintiffs	11:42	17 it seems to me like you kind of want to have it	11:44
18 would lose?	11:42	18 both ways. When I ask you a specific question and	11:44
19 A. According to my notes, yes.	11:42	19 said -- and asked whether this is what that means,	11:44
20 Q. I want you to tell me if that's what you	11:42	20 you said no, that's not what it means. When I ask	11:44
21 were told, Dr. Bliesner.	11:42	21 you generally what it means, you respond by saying	11:44
22 A. I was told that, yes.	11:42	22 "I don't know."	11:44
23 Q. Okay. Below that --	11:42	23 MR. KERENSKY: Objection, form.	11:44
24 A. Uh-huh.	11:42	24 BY MR. ANDERTON:	11:44
25 Q. -- there's a bracketed or kind of like	11:42	25 Q. So, I mean --	11:44
	Page 147		Page 149
1 an almost box. It says "problem could be with."	11:42	1 A. I cannot definitively tell you where	11:44
2 That's W/sub potent for blend uniformity. What	11:42	2 this statement fits into this conversation. I	11:44
3 does that mean?	11:42	3 just cannot.	11:44
4 A. I think one of the attorneys asked me	11:42	4 Q. Okay. The next -- below that on the	11:44
5 that question so I just jotted it down.	11:42	5 left side there's like a phrase that says	11:44
6 Q. Who asked you?	11:43	6 "conscious indifference." "Gross negligence."	11:45
7 A. I don't recall.	11:43	7 Do you see that?	11:45
8 Q. You just jotted down the question they	11:43	8 A. Yes.	11:45
9 asked you?	11:43	9 Q. Why did you write that?	11:45
10 A. I did, yeah. There was points where	11:43	10 A. Because they were terms that they were	11:45
11 they asked think about this. Okay. So I jotted	11:43	11 throwing around. So I jotted them down so I could	11:45
12 it down.	11:43	12 try to figure out what it meant.	11:45
13 Q. So they told you that -- they told you	11:43	13 Q. On the very bottom right corner -- don't	11:45
14 that as you answered -- listened to and answered	11:43	14 turn the page just yet, Dr. Bliesner.	11:45
15 questions, you should -- you should remember that	11:43	15 A. Sorry.	11:45
16 the problem -- I assume that means with Digitek --	11:43	16 Q. There's another bracketed phrase that	11:45
17 could be with a blend uniformity or a sub-potent	11:43	17 says, "what is the likelihood of blend uniformity	11:45
18 product; right?	11:43	18 causing these super of sub-potent." I assume	11:45
19 A. No, I don't think that's the case	11:43	19 that's supposed to be super or sub potent?	11:45
20 necessarily. There was instruction going on here	11:43	20 A. I'm thinking that's probably what it was	11:45
21 with attorneys on top of it all. So some of this	11:43	21 supposed to be.	11:45
22 was, you know, go back, make a note of it, go back	11:43	22 Q. All right. So why did you make that	11:45
23 and explain to them my interpretation because they	11:43	23 note?	11:45
24 hadn't been exposed to any of this stuff before.	11:43	24 A. I don't know. I don't recall why I made	11:45
25 Q. "They" who?	11:43	25 that note. Again, it might have been a question	11:45

38 (Pages 146 to 149)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

	Page 150		Page 152
1	from one of the attorneys or. 11:45	1	"tell me all" with an extended ellipses, and then 11:48
2	Q. Did you discuss with the Plaintiffs' 11:45	2	it says, "give them roman numerals." What does 11:48
3	counsel on the 24th the notion of the difference 11:45	3	that mean? 11:48
4	between double-thick tablets and tablets that were 11:45	4	A. That's the lists that we came up with. 11:48
5	either super or sub-potent? 11:45	5	Q. Okay. "We" came up with? 11:48
6	A. The difference between? 11:46	6	A. Well, I gave it. Somebody wrote it on 11:48
7	Q. Yeah. 11:46	7	the board as I was saying it. 11:48
8	A. I don't recall that conversation, the 11:46	8	Q. Oh, you had a white board? 11:48
9	difference between. 11:46	9	A. Uh-huh. 11:48
10	Q. Did they tell you to make sure that you 11:46	10	Q. Where was this? 11:48
11	kept the door open -- to use your terminology -- 11:46	11	A. The conference room. 11:48
12	to give testimony that there were either super 11:46	12	Q. Where? 11:48
13	potent or sub-potent tablets produced? 11:46	13	A. In the hotel next door. 11:48
14	A. Do we need to read this back? 11:46	14	Q. At the Hyatt? 11:48
15	Q. We do, please. 11:46	15	A. What was it? Sheraton, I believe. 11:48
16	A. Okay. 11:46	16	Q. Okay. 11:48
17	(Whereupon, the testimony was read back 11:46	17	A. Uh-huh. 11:48
18	by the court reporter, as recorded above) 11:46	18	Q. Who was writing on the board? 11:48
19	THE WITNESS: I don't recall being 11:46	19	A. At that time? I think it was Mike. 11:48
20	specifically asked to leave the door open or 11:46	20	Q. Mike Kerensky? 11:49
21	that issue in particular with respect to super 11:46	21	A. Yes. 11:49
22	or sub-potent. 11:46	22	Q. I'm sorry I missed that. 11:49
23	MR. ANDERTON: Okay. I need to go off 11:46	23	So what -- help me out here with context, 11:49
24	the record for about 30 seconds. Mike, stay 11:47	24	then. You were collectively generating a list and 11:49
25	close. 11:47	25	the list that is set forth in Roman numerals in 11:49
	Page 151		Page 153
1	THE VIDEOGRAPHER: The time is 11:47	1	Exhibit 152? 11:49
2	11:46 a.m. We're going off the record 11:47	2	A. Yes. 11:49
3	briefly. 11:47	3	Q. And then you wrote them down as you 11:49
4	(Short break) 11:47	4	collectively generated that list? 11:49
5	THE VIDEOGRAPHER: The time is 11:47	5	A. As I was pontificating, somebody said 11:49
6	a.m. We're back on the record. 11:47	6	oh, okay. I believe it was, if I recall, Mike 11:49
7	BY MR. ANDERTON: 11:47	7	just writing it down. It was all off the top of 11:49
8	Q. All right. So turn to the next page of 11:47	8	my head. 11:49
9	Exhibit 153, Dr. Bliesner. 11:47	9	Q. Well, but -- okay. 11:49
10	A. Yes. 11:47	10	A. Uh-huh. 11:49
11	Q. On the top it says, the second line of 11:47	11	Q. Go to the next page. The very last page 11:50
12	that next page it says "think:" 11:47	12	of Exhibit 153. 11:50
13	A. Uh-huh. 11:47	13	A. Last page? 11:50
14	Q. "Can I ask this question?" What does 11:47	14	Q. Yeah. And let me ask you this: 11:50
15	that mean? 11:48	15	A. Uh-huh. 11:50
16	A. I think I had a question can I ask -- as 11:48	16	Q. Have you given a copy of these notes to 11:50
17	I'm being deposed, can I ask questions back of the 11:48	17	the lawyers? 11:50
18	people who are asking me questions. 11:48	18	A. I don't know. I really don't know if 11:50
19	Q. What did they tell you? 11:48	19	they've got a copy of it. 11:50
20	A. They said no, you're pretty much 11:48	20	Q. You would have made the copies; right, 11:50
21	supposed to sit there and answer questions, if I 11:48	21	Dr. Bliesner? 11:50
22	remember right. 11:48	22	A. Not necessarily. 11:50
23	Q. Okay. 11:48	23	Q. Your wife would have made them for you? 11:50
24	A. Uh-huh. 11:48	24	A. The notes were done in the conference 11:50
25	Q. Next a little bit below that it says 11:48	25	room when we prepped the day before. 11:50

39 (Pages 150 to 153)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 154			Page 155		
1	Q. And you think the lawyers maybe took	11:50	1	A. Unless I finish reviewing this report, I	11:53
2	them and made copies of them?	11:50	2	can't answer that question.	11:53
3	A. I have no idea. They perhaps could	11:50	3	MR. ANDERTON: Let's go off the record	11:53
4	have.	11:50	4	and allow you to do that.	11:53
5	Q. On that last page --	11:50	5	THE VIDEOGRAPHER: The time is now	11:53
6	A. Uh-huh.	11:50	6	a.m. We're going off the record	11:53
7	Q. -- number two says NTI. I take it	11:51	7	briefly.	11:53
8	that's supposed to mean narrow therapeutic index?	11:51	8	(Short break)	12:01
9	A. I don't know.	11:51	9	THE VIDEOGRAPHER: The time is	12:01
10	Q. You don't know?	11:51	10	p.m. We are back on record.	12:01
11	A. I really don't.	11:51	11	BY MR. ANDERTON:	12:01
12	Q. Bracket references the EIR 2008, "95	11:51	12	Q. Dr. Bliesner, I asked you a question or	12:01
13	pages. Will ask." What does that mean?	11:51	13	I started to ask you a question about your	12:01
14	A. I don't know.	11:51	14	opinions in this case.	12:01
15	Q. At the very bottom it says, "Pills	11:51	15	A. Uh-huh, yes.	12:01
16	probably got out there."	11:51	16	Q. And in response you said "we know".	12:01
17	Do you see that?	11:51	17	Know --	12:02
18	A. I do.	11:51	18	A. Uh-huh.	12:02
19	Q. You wrote that; right?	11:51	19	Q. -- adulterated product reached the	12:02
20	A. I did write that.	11:51	20	market.	12:02
21	Q. What's it mean?	11:51	21	A. Yes.	12:02
22	A. It means at the end of the day, after	11:51	22	Q. I then asked you the basis for your	12:02
23	looking at my report again and having these	11:51	23	testimony that we know adulterated product reached	12:02
24	discussions that I was convinced that it was	11:51	24	the market and you said -- you asked to review	12:02
25	probable that more than just two or three or	11:52	25	your report which you just did; right?	12:02

Page 155			Page 157		
1	whatever, double-thick or whatever, thin tablets	11:52	1	A. Yes.	12:02
2	that were out there got out there. I was	11:52	2	Q. Have you reviewed your report and are	12:02
3	convinced with the data.	11:52	3	you able to answer my questions on how we know or	12:02
4	Q. Which brings us back to the underlying	11:52	4	you think you know adulterated product reached the	12:02
5	question that prompted all of this.	11:52	5	market?	12:02
6	A. Uh-huh.	11:52	6	A. I have a -- general idea is to go back	12:02
7	Q. Your opinion indicates that you believe	11:52	7	and specifically look at the wording, I would have	12:02
8	adulterated product reached the market.	11:52	8	to go to the appendices, but I can give you the	12:02
9	A. Well, we know it reached the market. We	11:52	9	references.	12:02
10	have a couple of circumstances where we know that	11:52	10	Q. You've got a 90-some page document in	12:02
11	it did.	11:52	11	front of you.	12:02
12	Q. Okay. And when you say a couple of	11:52	12	A. Yes.	12:02
13	circumstances, you're talking about the 2004	11:52	13	Q. You need to go outside that 90-page	12:02
14	circumstance and the 2008 allegations that	11:52	14	document to answer my question about how we -- how	12:02
15	double-thick tablets reached the market.	11:52	15	you think you know adulterated product reached the	12:02
16	Am I correct about that?	11:52	16	market?	12:02
17	A. Not necessarily because we stopped	11:52	17	A. Yeah, I want to make sure I'm answering	12:02
18	sometime back going through, picking out to make	11:52	18	the question completely.	12:02
19	sure that there was other points other than what	11:52	19	Q. Well, tell me what you know from	12:03
20	you're pointing out right there.	11:53	20	reviewing the report.	12:03
21	Q. Are you aware of any other circumstances	11:53	21	A. From reviewing the report on page 79,	12:03
22	that suggest to you that we -- that you know	11:53	22	number 12, that there was a Class II recall	12:03
23	double-thick tablets reached the market?	11:53	23	initiated through variation in tablet size	12:03
24	A. In your original question --	11:53	24	resulting in sub or super potent drug product,	12:03
25	Q. I'm asking you that question now.	11:53	25	according to reference attachment D5.	12:03

40 (Pages 154 to 157)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 158				Page 160			
1	Q.	Was that Digitek?	12:03	1	Q.	Yeah?	12:05
2	A.	I don't recall. I'd have to look it up.	12:03	2	A.	And this is where I would have to go	12:05
3	Q.	What was the year of that?	12:03	3		back and specifically look because I'm not sure	12:05
4	A.	1990.	12:03	4		whether these are returned products or not, but	12:05
5	Q.	1990?	12:03	5		overweight tablets were found during packaging;	12:05
6	A.	Uh-huh.	12:03	6		okay? That one I'm...	12:05
7	Q.	21 years ago?	12:03	7	Q.	What number are you referring to?	12:05
8	A.	Yes.	12:03	8	A.	47, 47.	12:05
9	Q.	Okay. What else do you know from	12:03	9	Q.	47?	12:05
10		reviewing your report?	12:03	10	A.	Yeah. A39 reference. That's why I	12:05
11	A.	Page 81, June 2004, complaint received	12:03	11		wanted to look at it because I'm not sure whether	12:05
12		from a pharmacist in Bellingham, Washington,	12:03	12		that has to do with stuff that made it to the	12:05
13		regarding thick Digoxin tablet. MI confirms	12:03	13		market or they caught it within the facility.	12:06
14		thickness. No definitive root cause found.	12:04	14	Q.	Would reference number 47, your	12:06
15	Q.	2004, a single tablet; right?	12:04	15		reference number 47 tell you that?	12:06
16	A.	I would have to look at the reference to	12:04	16	A.	A39.	12:06
17		determine whether it was one tablet or not.	12:04	17	Q.	I'm sorry. Would that tell you whether	12:06
18	Q.	Dr. Bliesner, this is your report;	12:04	18		it made it to market?	12:06
19		right?	12:04	19	A.	More than likely whether this was done	12:06
20	A.	It is my report, yes, sir.	12:04	20		internally and it wasn't returned.	12:06
21	Q.	Now this is why this takes so long. Is	12:04	21	Q.	Okay. What else from your report?	12:06
22		it more than a single tablet?	12:04	22	A.	Number 49 on page 84, Mylan acknowledges	12:06
23		MR. KERENSKY: He doesn't need be	12:04	23		pharmacist identifying double-thick product in	12:06
24		lectured about how long it takes. We need you	12:04	24		marketplace.	12:06
25		to ask questions.	12:04	25	Q.	Okay.	12:06

Page 159				Page 161			
1		MR. ANDERTON: I need him to answer	12:04	1	A.	A58.	12:06
2		questions, Mike.	12:04	2	Q.	Anything else?	12:06
3		MR. KERENSKY: He's answering them.	12:04	3	A.	From what I can see, no.	12:06
4		MR. ANDERTON: No, he's not.	12:04	4	Q.	Okay. Now, this binder -- oh, Phil	12:06
5		MR. KERENSKY: Well, when you ask a real	12:04	5		would you mark this, please?	12:06
6		broad question about tell me everything you	12:04	6		(Whereupon, Exhibit 154 was marked for	12:07
7		know, it's going to take time, bro?	12:04	7		identification)	12:07
8		MR. ANDERTON: Bro?	12:04	8		Dr. Bliesner, will you look at the binder	12:07
9		MR. KERENSKY: Bro.	12:04	9		that's marked as Exhibit 154 and find your	12:07
10	BY MR. ANDERTON:		12:04	10		reference attachment A36, please. I'm sorry. I	12:07
11	Q.	Dr. Bliesner.	12:04	11		misspoke. A39, please.	12:07
12	A.	Yes.	12:04	12		Did you find A36?	12:08
13	Q.	Your report on page 81 refers to a	12:04	13	A.	I'm just double checking here. Does not	12:08
14		single thick tablet; right?	12:04	14		appear to be the direct reference that I thought	12:08
15	A.	Unless I go back and pull up those	12:05	15		it was going to.	12:08
16		reference, I can't tell you whether it's one or	12:05	16	Q.	I'm sorry. A39. I misspoke again. Did	12:08
17		more.	12:05	17		you find A39?	12:08
18	Q.	You can't?	12:05	18	A.	I did find A39, but it does not appear	12:08
19	A.	No, definitively. I would be guessing	12:05	19		to me to be the reference that I referenced	12:08
20		unless I go back to that primary reference.	12:05	20		here -- A39.	12:08
21	Q.	All right. Moving on.	12:05	21	Q.	What is A39, Doctor?	12:09
22		What else from your report supports your	12:05	22	A.	A39 is response to the FDA 483 issued to	12:09
23		conclusion that adulterated Digitek reached the	12:05	23		Activis on 5/20/2008.	12:10
24		market?	12:05	24	Q.	Let's not take our common sense hats	12:10
25	A.	On page 87.	12:05	25		off; okay? Let's think about this logically.	12:10

41 (Pages 158 to 161)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 162			Page 164		
1	A. Okay.	12:10	1	Q. Okay.	12:15
2	Q. Your paragraph 47 on page 87 of your	12:10	2	A. Okay.	12:15
3	report refers to an investigation of Digoxin	12:10	3	Q. So -- well, suffice to say,	12:15
4	tablets, lot 8022881.	12:10	4	Dr. Bliesner, that there's ample information out	12:16
5	A. Uh-huh.	12:10	5	there in the record making very clear that that	12:16
6	Q. For overweight tablets --	12:10	6	batch was in fact rejected and never went to	12:16
7	A. Uh-huh.	12:10	7	market.	12:16
8	Q. -- which were found during packaging	12:10	8	You don't have any information that	12:16
9	right?	12:10	9	contradicts that, do you?	12:16
10	A. Uh-huh.	12:10	10	A. Not to my knowledge, no.	12:16
11	Q. You have to say yes or no, please.	12:10	11	Q. Okay. So, if that batch was rejected	12:16
12	A. Yes, I'm sorry.	12:10	12	that -- that -- the circumstances relating to or	12:16
13	Q. Okay.	12:10	13	set forth in your paragraph 47 on page 18 of your	12:16
14	A. I'm sorry.	12:10	14	report do not constitute any evidence that	12:16
15	Q. Do you cite that as support in your	12:10	15	defective or adulterated Digitek -- I want to make	12:16
16	report, in the body of your conclusion that	12:10	16	this clear. That adulterated Digitek actually	12:16
17	product actually made it to market?	12:10	17	made it to market, did they?	12:16
18	A. What I was asked to review, I was asked	12:10	18	A. That is correct.	12:16
19	to pick out things and I'm not sure whether these	12:10	19	Q. Okay. You also referred to -- and so	12:16
20	were picked up in site or they were returned	12:10	20	that we're clear, you also made reference to that	12:16
21	products or something like that.	12:10	21	batch 8022801 from paragraph 47 on page 87. So	12:17
22	Q. Now answer my question.	12:10	22	your prior testimony about that possibly	12:17
23	A. Okay.	12:10	23	supporting a statement that we know adulterated	12:17
24	Q. Do you cite that batch and the	12:10	24	product made it to market, that's not accurate	12:17
25	circumstances -- and any circumstances relating to	12:10	25	with respect to any circumstances relating to	12:17

Page 163			Page 165		
1	that batch in the body of your report as an	12:11	1	batch 8022801, is there?	12:17
2	indication that product -- defective product or	12:11	2	A. What page was that?	12:17
3	adulterated product made it to market?	12:11	3	Q. 87.	12:17
4	A. This is the citation. Criminal	12:11	4	A. No, it's the same -- same statement.	12:17
5	investigation, QA hold pending.	12:11	5	It's just information put in a different place.	12:17
6	Q. Dr. Bliesner.	12:11	6	Q. Okay.	12:17
7	A. I'm trying to answer your question, sir.	12:11	7	A. Uh-huh.	12:17
8	Q. I asked you if you cite it in your	12:11	8	Q. All right.	12:17
9	report. You're now looking at something other	12:11	9	A. We were going to check on number 49.	12:17
10	than your report.	12:11	10	Q. We'll get there.	12:17
11	A. Right, because I've got to go back --	12:11	11	A. Okay.	12:17
12	Q. How do you determine --	12:11	12	Q. The -- Dr. Bliesner, so we've eliminated	12:17
13	A. Because I want to see where the	12:11	13	batch 80228. The circumstances in 2004 where a	12:18
14	investigation is, if it's cited in the reference	12:11	14	pharmacist found a tablet in the market, was that	12:18
15	to make sure that the reference is correct.	12:11	15	part of the recalled product?	12:18
16	Q. Okay.	12:12	16	A. Which recall?	12:18
17	A. Okay?	12:12	17	Q. The 2008 recall of Digitek.	12:18
18	Q. Okay.	12:12	18	A. The product for the?	12:18
19	A. I'm not messing with you.	12:12	19	Q. The tablet that was found in the market	12:18
20	Q. You actually are.	12:12	20	in 2004, was that part of the recalled product?	12:18
21	A. I'm just trying to get the right	12:12	21	A. Not to my knowledge.	12:18
22	answer. No, sir, I'm not.	12:12	22	Q. The expiration period for this product	12:18
23	That reference does not support the statement	12:15	23	is two years. Are you aware of that?	12:18
24	that product made it to market. That specific	12:15	24	A. I am not.	12:18
25	reference does not.	12:15	25	Q. Okay. You'll take my word for it?	12:18

42 (Pages 162 to 165)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 166			Page 168		
1	A. I'll take your word for it.	12:18	1	Q. Okay. Who was the director of	12:20
2	Q. So if a tablet was found in the market	12:18	2	manufacturing in 2008, do you know?	12:20
3	in 2004 and was manufactured no later than 2004	12:18	3	A. I'd have to go back.	12:20
4	and therefore was no longer in the market and	12:18	4	Q. I'm sorry. In 2007.	12:20
5	within expiration as of 2008; correct?	12:18	5	A. I'd have to go back and look at that.	12:20
6	A. 2004, two years I would say yes, that's	12:18	6	Q. It was Rick Dowling.	12:20
7	fair.	12:18	7	A. Okay.	12:20
8	Q. Okay. And again, there's plenty of	12:19	8	Q. You'll take my word for that?	12:20
9	evidence out there that speaks to what or was not	12:19	9	A. Sure.	12:20
10	part of the recall product.	12:19	10	Q. When was Rick Dowling hired?	12:20
11	Which leaves us -- and the 1990 circumstances	12:19	11	A. I'd have to go back and look that up.	12:20
12	certainly have nothing, no -- none of the product	12:19	12	Q. Was he employed in 1990?	12:20
13	that was involved in the circumstances you cited	12:19	13	A. I'd have to go back and look it up.	12:20
14	in 1990 were part of the 2008 recall; correct?	12:19	14	Q. Because Activis in 1990 was Amide;	12:21
15	A. Not part of the 2008 recall, no.	12:19	15	correct?	12:21
16	Q. Okay. All right.	12:19	16	A. I believe it was.	12:21
17	A. It may have impacted the product,	12:19	17	Q. Were they making Digitek as of 1990?	12:21
18	though.	12:19	18	A. I'd have to look that up, but it's a	12:21
19	THE VIDEOGRAPHER: We've got five minutes	12:19	19	possibility they were.	12:21
20	left on the tape.	12:19	20	Q. It is?	12:21
21	BY MR. ANDERTON:	12:19	21	A. Yes.	12:21
22	Q. Okay. It may have impacted what	12:19	22	Q. Their ANDA was approved when?	12:21
23	product?	12:19	23	A. They were releasing product by the batch	12:21
24	A. We're not sure because the reference is	12:19	24	release certification process back then. So they	12:21
25	just for a recall for double-thick, double thin.	12:19	25	submitted and sold product based on that and not	12:21
Page 167			Page 169		
1	The information I was provided doesn't	12:19	1	the ANDA.	12:21
2	specifically say what the product is.	12:19	2	Q. If it's true --	12:21
3	Q. Okay.	12:19	3	A. Uh-huh.	12:21
4	A. There was indications that they've had	12:19	4	Q. -- that Activis -- or Amide rather --	12:21
5	problems with double-thick, double thin or thin or	12:19	5	wasn't making Digoxin until 1995, then the 1990	12:21
6	thick tablets in days gone by in the manufacturing	12:19	6	circumstances have no bearing on your conclusion	12:21
7	process.	12:19	7	that adulterated Digitek -- that your supposed	12:21
8	Q. And so you're willing to infer that	12:19	8	conclusion that we know adulterated Digitek made	12:21
9	something that happened in 1990 was still	12:19	9	it to market; correct?	12:21
10	occurring in 199-- or in 2008, 18 years later?	12:19	10	A. I don't know if I understand that	12:21
11	A. I think it's fair to say that the	12:20	11	question.	12:21
12	information that's there in documents that I	12:20	12	Q. You don't understand it because it was a	12:21
13	reviewed showed that the same people who were in	12:20	13	very poorly worded question. So I'm going to	12:21
14	charge of the quality and manufacturing back then	12:20	14	start that one over.	12:22
15	are the same people that were there later down the	12:20	15	If it's true that Amide didn't start	12:22
16	road. The same processes -- I'm trying to think	12:20	16	manufacturing Digitek until 1995, then the	12:22
17	when the ANDAs were, the equipment was. So if	12:20	17	circumstances you refer to about a 1990 recall	12:22
18	people and equipment were in place and obviously	12:20	18	have nothing to do with your conclusion in your	12:22
19	they had problems with quality systems difficulty,	12:20	19	report that we know adulterated Digitek reached	12:22
20	else they wouldn't have had all the problems with	12:20	20	the market; correct?	12:22
21	the FDA.	12:20	21	A. I don't think you can say that.	12:22
22	So there were documented problems with the	12:20	22	Q. They weren't making it.	12:22
23	quality systems, same people and mostly like the	12:20	23	A. They were making Digoxin very early on.	12:22
24	same equipment on the stuff that occurred later	12:20	24	Q. Dr. Bliesner, if they didn't start	12:22
25	on.	12:20	25	making it until 1995, they couldn't -- the recall	12:22

43 (Pages 166 to 169)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 170		Page 172	
1	in 1990 could not have been Digoxin; correct? 12:22	1	A. Most likely, yes. 12:54
2	A. I'm not sure without going back and 12:22	2	Q. And the 2008 batch 80228 was rejected 12:54
3	reviewing the record when they actually started 12:22	3	and never made it to market. That leaves the 12:54
4	making Digoxin tablets. 12:22	4	tablet referenced in -- 12:55
5	Q. Now answer my question. 12:22	5	A. Well, that was that -- just that one lot 12:55
6	A. Okay. 12:22	6	that we talked about that was rejected. 12:55
7	Q. If they didn't start making it until 12:22	7	Q. I understand. 12:55
8	1995, the 1990 recall circumstances could not have 12:22	8	A. Okay. 12:55
9	been a recall of Digoxin; correct? 12:23	9	Q. But you've identified for me -- I gave 12:55
10	A. If they did not, that's correct. 12:23	10	you a considerable amount of time. 12:55
11	Q. Okay. 12:23	11	A. Uh-huh. 12:55
12	A. If. But we don't know for sure. 12:23	12	Q. Let's back this up, Dr. Bliesner. 12:55
13	Q. But we do, Dr. Bliesner. 12:23	13	I asked you about your conclusion in this 12:55
14	A. We do? 12:23	14	case. 12:55
15	Q. Okay. 12:23	15	A. Uh-huh. 12:55
16	A. Yes. 12:23	16	Q. And about the conclusion that 12:55
17	Q. We do. 12:23	17	adulterated Digitek was released to market and you 12:55
18	THE VIDEOGRAPHER: You have about two 12:23	18	said very clearly "we know that adulterated defect 12:55
19	minutes left. 12:23	19	made it to market." 12:55
20	MR. ANDERTON: Let's break for lunch. 12:23	20	A. Yes. 12:55
21	THE VIDEOGRAPHER: The time is 12:23	21	Q. I gave you almost a half hour to review 12:55
22	12:22 p.m. We're going off the record. 12:23	22	your report and other related documents to come up 12:55
23	(Short break for lunch) 12:52	23	with evidence which you believe indicates that you 12:55
24	THE VIDEOGRAPHER: The time is now 12:52	24	know adulterated Digitek made it to market. 12:55
25	12:52 p.m. We are back on the record. This 12:53	25	A. Uh-huh. 12:55
Page 171		Page 173	
1	is the beginning of tape five. 12:53	1	Q. And you identified all of those 12:55
2	BY MR. ANDERTON: 12:53	2	instances and circumstances; right? 12:55
3	Q. Dr. Bliesner, would you look at page 9 12:53	3	A. With the information I have reviewed, 12:55
4	of your report, please? 12:53	4	yes. 12:55
5	A. Sure, yes. 12:53	5	Q. Okay. And you've identified everything 12:55
6	Q. You see paragraph four on page 9? 12:53	6	that you're aware of; correct? 12:56
7	A. Yes. 12:53	7	A. In the documents that I was -- reviewed, 12:56
8	Q. That indicates that in June of 1995 the 12:53	8	yes. 12:56
9	FDA issued a certification to Amide which allowed 12:53	9	Q. Dr. Bliesner. 12:56
10	Amide to manufacture and sell Digoxin under the 12:53	10	A. Yes. 12:56
11	batch certification program; right? 12:53	11	Q. Have you identified every instance that 12:56
12	A. Correct. 12:53	12	you are aware of where you believe adulterated 12:56
13	Q. Does that refresh your recollection as 12:54	13	Digitek made it to market? 12:56
14	to when Amide began manufacturing and distributing 12:54	14	A. In the documents I reviewed, yes. 12:56
15	Digitek and whether it was as far back as 1990? 12:54	15	Q. Doctor -- 12:56
16	A. Yes. 12:54	16	A. There may be other documents out there 12:56
17	Q. Okay. What we know now is that the 1990 12:54	17	that would support the -- 12:56
18	recall was not Digitek or Digoxin; correct? 12:54	18	Q. Are you aware of those? 12:56
19	A. Most likely. 12:54	19	A. I haven't reviewed everything that's on 12:56
20	Q. And so then as I understand it, you 12:54	20	there, been put out. So I can't -- I can't say 12:56
21	agree that the 2004 tablet was not part of the 12:54	21	whether I'm aware of it or not. 12:56
22	recalled Digitek; right? 12:54	22	Q. If you haven't reviewed it, can you be 12:56
23	A. Based on expiration date and the fact 12:54	23	aware of what's in it? Is that possible? 12:56
24	that it was two years and then later on, yes. 12:54	24	A. No, that's what I'm saying. There are 12:56
25	Q. The 1990 recall was not Digitek; right? 12:54	25	additional documents and reports and things like 12:56

44 (Pages 170 to 173)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

<p style="text-align: right;">Page 174</p> <p>1 that I'm sure have since become available and I 12:56</p> <p>2 have not reviewed it. The documents that I 12:56</p> <p>3 reviewed, the statement is correct. 12:56</p> <p>4 Q. We're going to stay here all afternoon 12:57</p> <p>5 until you answer my question. 12:57</p> <p>6 A. That's fine. 12:57</p> <p>7 Q. Are you aware -- do you know of any 12:57</p> <p>8 circumstances you haven't identified that you 12:57</p> <p>9 believe indicate adulterated Digitek made it to 12:57</p> <p>10 market? 12:57</p> <p>11 A. You see, I still don't understand when 12:57</p> <p>12 you say "any and all" and "aware." The documents 12:57</p> <p>13 I've reviewed, that I was told to review and, you 12:57</p> <p>14 know, looked at and reviewed are the ones that 12:57</p> <p>15 I've built my report off of, and that's the 12:57</p> <p>16 circumstances where I found it. 12:57</p> <p>17 I can't make a statement as broad as aware or 12:57</p> <p>18 whatever because there may be others out there. I 12:57</p> <p>19 don't know. 12:57</p> <p>20 Q. You can't tell me what you know? 12:57</p> <p>21 A. I'm telling you -- 12:57</p> <p>22 Q. My question -- 12:57</p> <p>23 A. -- what I know based on this, sir. 12:57</p> <p>24 Q. My question was do you know of any other 12:57</p> <p>25 circumstances? 12:57</p>	<p style="text-align: right;">Page 176</p> <p>1 THE WITNESS: I don't understand when you 12:59</p> <p>2 say "injecting." 12:59</p> <p>3 MR. ANDERTON: You think because of your 12:59</p> <p>4 prep sessions with counsel that you're 12:59</p> <p>5 absolutely required to qualify everything you 12:59</p> <p>6 say to leave doors open, as your notes say. 12:59</p> <p>7 This is a concise -- 12:59</p> <p>8 THE WITNESS: That's not true. 12:59</p> <p>9 MR. ANDERTON: It's absolutely true. 12:59</p> <p>10 THE WITNESS: It is not true. 12:59</p> <p>11 MR. ANDERTON: You wait till you watch 12:59</p> <p>12 the video. This is a very concise, very 12:59</p> <p>13 direct question. Phil, would you read it 12:59</p> <p>14 back? 12:59</p> <p>15 (Whereupon, the testimony was read 12:59</p> <p>16 back by the court reporter, as recorded above) 12:59</p> <p>17 THE WITNESS: Other than what I've 12:59</p> <p>18 reviewed -- which you state in there -- no. 01:00</p> <p>19 BY MR. ANDERTON: 01:00</p> <p>20 Q. Other than what you've identified. Stop 01:00</p> <p>21 injecting what you've reviewed into this. I'm 01:00</p> <p>22 asking you what you know, Dr. Bliesner. And we're 01:00</p> <p>23 going to ask this for hours until you answer my 01:00</p> <p>24 question. 01:00</p> <p>25 You have identified certain circumstances that 01:00</p>
<p style="text-align: right;">Page 175</p> <p>1 A. Not to the documents I've reviewed. 12:57</p> <p>2 Q. Dr. Bliesner, do you know of any other 12:57</p> <p>3 circumstances that indicate defective Digitek -- 12:57</p> <p>4 adulterated -- let me ask this correctly. 12:58</p> <p>5 Do you know, do you have knowledge from any 12:58</p> <p>6 source other than those that you've identified? 12:58</p> <p>7 A. Other than those that I've reviewed. 12:58</p> <p>8 Q. No. Other than that you've identified, 12:58</p> <p>9 do you personally have knowledge as we sit here 12:58</p> <p>10 today of any circumstances indicating adulterated 12:58</p> <p>11 Digitek made it to market other than those you've 12:58</p> <p>12 identified? 12:58</p> <p>13 A. The two references, no. 12:58</p> <p>14 Q. Other than those you've identified, 12:58</p> <p>15 you're not aware of any other circumstances 12:58</p> <p>16 indicating that defective -- I keep saying that -- 12:58</p> <p>17 that adulterated Digitek was released to market; 12:58</p> <p>18 is that correct? 12:58</p> <p>19 A. To this point, no, that is correct. 12:58</p> <p>20 MR. ANDERTON: Okay. I want this to be 12:58</p> <p>21 clear. You keep injecting all this extra 12:58</p> <p>22 stuff. So, Phil, I'm going to ask you to read 12:58</p> <p>23 my last question back and I want you to answer 12:58</p> <p>24 it very clearly, okay, without injecting all 12:59</p> <p>25 kinds of additional stuff. 12:59</p>	<p style="text-align: right;">Page 177</p> <p>1 you believe indicate adulterated Digitek was 01:00</p> <p>2 released to market; is that correct? 01:00</p> <p>3 A. Yes, yes. 01:00</p> <p>4 Q. Other than the ones you've identified, 01:00</p> <p>5 are you aware of any other circumstances that you 01:00</p> <p>6 believe indicate adulterated Digitek was released 01:00</p> <p>7 to market? 01:00</p> <p>8 A. No. 01:00</p> <p>9 Q. Thank you. 01:00</p> <p>10 So what we have haven't discussed then is the 01:00</p> <p>11 single tablet that is referenced in -- can you 01:00</p> <p>12 turn to your report at page 87. Let me know when 01:00</p> <p>13 you are there. 01:01</p> <p>14 A. I am on page 87, sir. 01:01</p> <p>15 Q. All right. Do you see paragraphs 46 and 01:01</p> <p>16 49? 01:01</p> <p>17 A. 46, yes. 01:01</p> <p>18 Q. Okay. 01:01</p> <p>19 A. 49, yes. 01:01</p> <p>20 Q. All right. So to be clear, we talked 01:01</p> <p>21 about the 1990 circumstances and we now know that 01:01</p> <p>22 that had nothing to do with Digitek; right? 01:01</p> <p>23 A. Most likely no. 01:01</p> <p>24 Q. We talked about the 2004 circumstances 01:01</p> <p>25 and we now know that that was not product that was 01:01</p>

45 (Pages 174 to 177)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 178			Page 180		
1	part of the Digitek recall; right?	01:01	1	Q. I understand.	01:09
2	A. That is correct.	01:01	2	A. Okay.	01:09
3	Q. And we talked about -- or we talked	01:01	3	Q. Have you seen that document before?	01:09
4	about the 2008 batch 80228, which is part of	01:01	4	A. I believe I have, yes.	01:09
5	paragraph 47 here, and we know that because that	01:02	5	Q. Okay. Turn to page 60 of your report,	01:09
6	batch was rejected, it also doesn't show anything	01:02	6	please.	01:09
7	about product making it to market.	01:02	7	A. Okay.	01:09
8	A. With that batch, no.	01:02	8	Q. In fact this document is what you list	01:09
9	Q. Correct?	01:02	9	as your reference A58; isn't that right?	01:09
10	A. Yes.	01:02	10	A. No.	01:10
11	Q. Talking only about that paragraph,	01:02	11	Q. No?	01:10
12	Dr. Bliesner.	01:02	12	A. It's got a different control number on	01:10
13	A. Okay, okay.	01:02	13	it than the one that I referenced, according to my	01:10
14	Q. Part of the issue here is that	01:02	14	report. This is Mylan 000932683.	01:10
15	Plaintiffs' lawyers have told you never to trust a	01:02	15	Q. Look at the next page, Doctor.	01:10
16	single word that comes out of my mouth, so...	01:02	16	A. Okay. There we go.	01:10
17	A. That's not true. They've never made a	01:02	17	Q. So there's an extra page on our Exhibit	01:10
18	statement even remotely related to that.	01:02	18	59A about, but what you refer to as A58, the	01:10
19	Q. Do you want me to find it in your	01:02	19	precise page is exactly your -- is the second page	01:10
20	notes?	01:02	20	of our 59A; is that correct?	01:10
21	Dr. Bliesner, what do you know about the	01:02	21	A. It looks like it.	01:10
22	circumstances referred to in paragraphs 46 and 49	01:02	22	Q. And are you -- do you have any reason to	01:10
23	from memory?	01:02	23	believe that the --	01:10
24	A. From memory, I couldn't tell you whether	01:03	24	A. Excuse me for just a second. Yes. It's	01:10
25	they were e-mails or they were reports. That's	01:03	25	the same, yes.	01:11

Page 179			Page 181		
1	what I can tell you from memory.	01:03	1	Q. All right. So this is an e-mail thread	01:11
2	Q. Okay. And does that mean that you also	01:03	2	between somebody at Mylan and somebody with an	01:11
3	don't remember the -- kind of the underlying	01:03	3	e-mail extension indicated as goldenliving.com,	01:11
4	circumstances, regardless of whether you remember	01:03	4	correct?	01:11
5	the source?	01:03	5	A. At the top level, yes.	01:11
6	A. Underlying circumstances?	01:03	6	Q. What's goldenliving.com, do you know?	01:11
7	Q. Yeah.	01:03	7	A. I have no idea.	01:11
8	A. 46 and 49?	01:03	8	Q. Is it a pharmacist?	01:11
9	Q. Yeah.	01:03	9	A. I have no idea.	01:11
10	A. No, I'd have to go back and look at the	01:03	10	Q. Yet on page 87 you characterize this as	01:11
11	records.	01:03	11	a pharmacist identifying a double-thick product	01:11
12	MR. ANDERTON: All right. Well, just	01:03	12	from the marketplace; right?	01:11
13	give me one moment. Let's go off the record	01:03	13	A. I say that based on the -- Pharm America	01:11
14	for a minute.	01:04	14	brought the statement in here, so...	01:11
15	THE VIDEOGRAPHER: The time is now	01:04	15	Q. Is Pharm America a pharmacist?	01:11
16	1:03 p.m. We're going off the record briefly.	01:04	16	A. I couldn't say for sure.	01:11
17	(Short break)	01:06	17	Q. You don't know?	01:11
18	THE VIDEOGRAPHER: The time is now	01:06	18	A. No.	01:12
19	1:06 p.m. We are back on the record.	01:06	19	Q. And you don't know if golden living is a	01:12
20	BY MR. ANDERTON:	01:06	20	pharmacist?	01:12
21	Q. Dr. Bliesner, I'm handing you a document	01:06	21	A. I could not say, no.	01:12
22	that has been marked as Exhibit 59A. Just take a	01:06	22	Q. Okay. But you were happy to write in	01:12
23	moment and look at that document, please.	01:06	23	your report that Mylan acknowledged a pharmacist	01:12
24	A. Sure. It trails off. It's not a	01:06	24	identifying a double-thick product in the market;	01:12
25	complete --	01:09	25	right? Look at page 87 of the report.	01:12

46 (Pages 178 to 181)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 182			Page 184		
1	A. Yes, yes. Thank you. I do use the word	01:12	1	A. I assume that's what the card is.	01:14
2	pharmacist. And based on this e-mail alone, I	01:12	2	Q. Are you an expert on blister packs?	01:14
3	couldn't definitively say in fact that was a	01:12	3	A. No.	01:14
4	pharmacist.	01:12	4	Q. Packaging?	01:14
5	Q. Okay. So that doesn't appear to be an	01:12	5	A. Packaging, no.	01:14
6	accurate characterization in your paragraph 49,	01:12	6	Q. Okay. Do you know whether this blister	01:14
7	does it?	01:12	7	pack was opaque on one side, like a lot of them	01:14
8	A. I'm sorry?	01:12	8	are?	01:14
9	Q. It doesn't appear to be an accurate	01:12	9	A. I've never seen a description of a	01:14
10	characterization in your 49, does it?	01:13	10	blister pack with respect to this.	01:14
11	A. It does not appear --	01:13	11	Q. You don't know anything about this	01:14
12	Q. Okay.	01:13	12	blister pack.	01:14
13	A. -- to be. I'm sorry. I heard	01:13	13	A. This one here?	01:14
14	inaccurate, so.	01:13	14	Q. Yeah?	01:14
15	Q. Well, I didn't say inaccurate. I said	01:13	15	A. I -- there's not enough information to	01:14
16	"an accurate," and I apologize if I spoke too	01:13	16	say.	01:14
17	quickly.	01:13	17	Q. Okay. And you don't know -- well, we	01:14
18	Turn to then the page that you actually refer	01:13	18	know that the tablet wasn't taken out of the	01:14
19	to as A58. Now, is this the -- am I correct that	01:13	19	blister pack and measured, don't we?	01:15
20	this document is the basis for your concluding	01:13	20	A. This particular one?	01:15
21	that adulterated Digitek that was part of the	01:13	21	Q. Yeah.	01:15
22	recall made it to market?	01:13	22	A. It says please advise that -- and,	01:15
23	A. One of the two.	01:13	23	again, I'm just -- this is all data we got here.	01:15
24	Q. What's the other one?	01:13	24	Q. I understand.	01:15
25	A. The other one was the pharmacist found a	01:13	25	A. "Please be advised that Lynn Carol, CSC,	01:15
Page 183			Page 185		
1	double-thick tablet, 47, what we talked about.	01:13	1	reports finding a card of Digoxin with one double	01:15
2	Q. But we know that wasn't part of the 2008	01:13	2	thickness tablet at GL" Gloucester. Whatever GL	01:15
3	recall.	01:13	3	is. I guess maybe that's their --	01:15
4	A. No, it was not part of the recall.	01:13	4	Q. An acronym for -- I can never say that.	01:15
5	Q. All right. So this is the sole piece of	01:13	5	Gloucester?	01:15
6	information that you have that provides any	01:13	6	A. Gloucester, yeah. "The card has four	01:15
7	indication that adulterated Digitek that was part	01:13	7	tablets remaining, one of which she reported was	01:15
8	of the 2008 recall made it to market.	01:13	8	obviously double-thick."	01:15
9	A. This is the only document I have	01:14	9	So there were four tablets remaining in the	01:15
10	reviewed thus far, that...	01:14	10	blister pack, one of which was identified as	01:15
11	Q. You're not aware of anything else.	01:14	11	double-thick.	01:15
12	You're not aware of any other document.	01:14	12	Q. Which she believed was double-thick.	01:15
13	A. I have not reviewed any documents.	01:14	13	A. She believed was double-thick, yes.	01:15
14	Q. That say that; right?	01:14	14	Q. Did you do anything to try to verify	01:15
15	A. No.	01:14	15	whether this report was accurate or could be	01:15
16	Q. Okay. Let's look at this.	01:14	16	accurate?	01:16
17	A. Uh-huh.	01:14	17	A. No.	01:16
18	Q. Particularly the page -- and we touched	01:14	18	Q. You just accepted it at face value?	01:16
19	on this a little bit last time, but I want to talk	01:14	19	A. I accepted it as data that supported	01:16
20	about it a little bit more thoroughly; okay?	01:14	20	double packaging.	01:16
21	A. Sure.	01:14	21	Q. At face value?	01:16
22	Q. A card of Digoxin with one	01:14	22	A. Yes, sir.	01:16
23	double-thickness tablet.	01:14	23	Q. You get paid for your analytical skills;	01:16
24	A. Uh-huh.	01:14	24	right?	01:16
25	Q. So it's in a blister pack; right?	01:14	25	A. I do, sir.	01:16

47 (Pages 182 to 185)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 186			Page 188		
1	Q. And you hold yourself out to out as an	01:16	1	Q. I wouldn't think so. Not for 550 an	01:18
2	individual possessing a high level of analytical	01:16	2	hour.	01:18
3	skills; correct?	01:16	3	Dr. Bliesner, I'm going to hand you a document	01:18
4	A. I would say that's a fair assessment.	01:16	4	that has been marked as Defendant's Exhibit 73,	01:18
5	Q. 550 an hour, that's a pretty talented	01:16	5	although it doesn't have a sticker on it.	01:18
6	analysis I would hope. And yet you didn't feel	01:16	6	A. Okay.	01:18
7	like this warranted any further analysis?	01:16	7	Q. Phil, would you mind putting a sticker	01:18
8	A. I don't think that's a fair statement.	01:16	8	on this one? Just says Exhibit 73.	01:18
9	Q. You didn't do any further analysis.	01:16	9	Have you seen that -- well, Dr. Bliesner, take	01:19
10	A. I didn't have -- first of all, I was	01:16	10	a moment to look at that document, please.	01:19
11	asked to review certain sets of documents --	01:17	11	A. Uh-huh.	01:19
12	Q. Right.	01:17	12	Q. Have you reviewed Exhibit 73?	01:23
13	A. -- that were available to me at that	01:17	13	A. I have, sir.	01:23
14	time.	01:17	14	Q. Have you see that document before?	01:23
15	Q. Right.	01:17	15	A. That's a good question.	01:23
16	A. And I reviewed those documents and	01:17	16	Q. Well, why don't you turn to page 47 of	01:23
17	extracted out of, you know, the thousands of pages	01:17	17	your report.	01:23
18	that I reviewed, those things that were	01:17	18	A. Okay.	01:23
19	pertinent. I identified, as you saw, that lended	01:17	19	Q. We'll make short work of that good	01:23
20	support to the fact that there were difficulties.	01:17	20	question.	01:23
21	Q. Okay.	01:17	21	A. Okay.	01:23
22	A. And by the time that rolled around,	01:17	22	Q. And for the record, that's two today.	01:23
23	there was no additional time to do any more	01:17	23	A. I'm sorry?	01:23
24	detailed investigation other than what I had	01:17	24	Q. That's two good questions today.	01:23
25	looked at.	01:17	25	Are you on page 47?	01:23
Page 187			Page 189		
1	Q. Well, in fact -- and so you didn't do	01:17	1	A. I am.	01:23
2	any more detailed investigation other than looking	01:17	2	Q. Do you see Exhibit -- or reference A36?	01:23
3	it with the Plaintiffs' attorneys.	01:17	3	A. I do.	01:23
4	A. With respect to this particular case?	01:17	4	Q. Do you see that you described that as	01:23
5	Q. Right.	01:17	5	being Plaintiffs' Exhibit M69?	01:23
6	A. No.	01:17	6	A. I do.	01:23
7	Q. Well, but you actually reviewed a	01:17	7	Q. Do you see the front of our Exhibit 63,	01:23
8	document that directly refutes the possibility of	01:17	8	indicating that that's M69?	01:23
9	this being accurate, didn't you?	01:17	9	A. It is.	01:23
10	A. What was that?	01:17	10	Q. And you see that that is a UDL internal	01:23
11	Q. I mean you certainly wouldn't have	01:17	11	investigation record?	01:23
12	ignored information that made it clear that this	01:17	12	A. Yes.	01:23
13	woman couldn't be correct, would you?	01:17	13	Q. From Digitek tablets? So what you're	01:23
14	A. I'm sorry. I didn't understand that	01:17	14	looking at as Defendant's 73 --	01:23
15	statement.	01:17	15	A. Yes.	01:23
16	Q. If you had seen information that made it	01:17	16	Q. -- is in fact your A36 reference;	01:23
17	clear that this report couldn't be correct, you	01:18	17	correct?	01:23
18	wouldn't have ignored that, would you?	01:18	18	A. Yes.	01:23
19	A. If I had seen information that	01:18	19	Q. So you looked at this document?	01:23
20	corroborated that?	01:18	20	A. Yes, sir.	01:24
21	Q. No, that contradicted it and made it	01:18	21	Q. In fact you made a point of highlighting	01:24
22	very clear that this observation couldn't be	01:18	22	in your report information which you thought was	01:24
23	correct, you wouldn't have ignored that, would	01:18	23	negative and adverse with respect to Activis. You	01:24
24	you?	01:18	24	made a point of indicating that there was a	01:24
25	A. Oh, absolutely not, no.	01:18	25	complaint about some tablets; right?	01:24

48 (Pages 186 to 189)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 190			Page 192		
1	A. Yes.	01:24	1	Q. Do you have any reason to believe that	01:26
2	Q. Can you turn to page 2 of Exhibit 73?	01:24	2	the information in this paragraph that you just	01:26
3	A. Yes.	01:24	3	read is inaccurate?	01:26
4	Q. Do you see the heading that says	01:24	4	A. Any reason?	01:26
5	"Examination of Retained Samples"?	01:24	5	Q. Yes.	01:26
6	A. Yes.	01:24	6	A. Based on my experience, unless I	01:26
7	Q. Read that paragraph please for me out	01:24	7	actually review an investigation report, I always	01:26
8	loud.	01:24	8	wonder if the summary is -- how accurate it is,	01:26
9	A. Sure. "Examination of retained	01:24	9	based on my experience.	01:26
10	samples. On 4/3/08, a visual examination of	01:24	10	Q. Do you have any reason to believe that	01:26
11	retains for both strengths of Digitek were	01:24	11	this paragraph and the information in this	01:26
12	completed. Upon evaluating the fit of the tablets	01:24	12	paragraph is inaccurate?	01:26
13	within the blister cavity, it was observed that	01:24	13	A. Based on the comment from the person who	01:26
14	both blister cavity sizes have minimal head space	01:24	14	saw it, I would say that there was a possibility	01:26
15	that would prevent tablets to be packaged with	01:25	15	that there was a double-thick tablet in that	01:26
16	double the thickness. If the tablet thickness	01:25	16	blister pack.	01:27
17	were to exceed the blister cavity size during	01:25	17	Q. So you're going to reject the	01:27
18	packaging, visible damage to the blister package	01:25	18	information of the packaging entity that says	01:27
19	would occur and the -- excuse me -- the equipment	01:25	19	their equipment would not allow packaging of	01:27
20	would experience a seal station overload, jamming	01:25	20	double-thick tablet in favor of an unreliable,	01:27
21	within the seal station, that would result in a	01:25	21	uncorroborated, unverified account of a woman in a	01:27
22	shutdown of the equipment.	01:25	22	nursing home that you characterized as a	01:27
23	This type of occurrence is documented on the	01:25	23	pharmacist.	01:27
24	inspection record and the batch record. As stated	01:25	24	MR. KERENSKY: Excuse me. Form.	01:27
25	above, there is no documentation in the batch	01:25	25	BY MR. ANDERTON:	01:27
Page 191			Page 193		
1	record of a machine- or inspection-related issues	01:25	1	Q. Is that what you're going to do?	01:27
2	involving tablet thickness."	01:25	2	A. What was his question. I'm sorry.	01:27
3	Q. Did you read that document before you	01:25	3	Q. His question was form. That means you	01:27
4	prepared your report. You obviously did; right?	01:25	4	get to answer my question. Phil, would you please	01:27
5	A. Yes sir.	01:25	5	read that back.	01:27
6	Q. You read that language?	01:25	6	MR. KERENSKY: That's correct.	01:27
7	A. Yes, sir.	01:25	7	(Whereupon, the testimony was read	01:28
8	Q. It makes it clear that the woman who	01:25	8	back by the court reporter, as recorded above)	01:28
9	thought she saw a double-thick tablet in a blister	01:25	9	THE WITNESS: Okay.	01:28
10	pack couldn't have been correct, doesn't it?	01:25	10	I am not rejecting this information.	01:28
11	A. I don't think you can say that	01:25	11	It's part of the data. As far as the	01:28
12	definitively. This is an internal investigation	01:25	12	characterization of a pharmacist, I don't have	01:28
13	report. This is what they report. There's --	01:25	13	any way to prove in fact it was a pharmacist	01:28
14	it's opinion based on their experience and	01:25	14	the way it's written in there. So this is	01:28
15	observation.	01:26	15	just additional data to -- that was discovered	01:28
16	Q. But it's not opinion. It's a very	01:26	16	during my review.	01:28
17	specific statement about the technical	01:26	17	BY MR. ANDERTON:	01:28
18	specifications and capabilities of their packaging	01:26	18	Q. You have given sworn testimony today --	01:28
19	equipment, isn't it?	01:26	19	A. Yes.	01:28
20	A. Perhaps.	01:26	20	Q. -- that her report, the information in	01:28
21	Q. What do you mean "perhaps"?	01:26	21	our Exhibit 59A allows you to say we know	01:29
22	A. It's an investigation summary.	01:26	22	adulterated Digitek was released to market.	01:29
23	Investigation summaries don't necessarily report	01:26	23	That's your sworn testimony.	01:29
24	all of the information in an accurate fashion on	01:26	24	A. My sworn testimony is we know that	01:29
25	what happened in the investigation.	01:26	25	there -- based on that pharmacist report in	01:29

49 (Pages 190 to 193)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 194			Page 196		
1	Bellingham, Washington, that that is true.	01:29	1	pharmacist, I can't come to a firm conclusion on	01:31
2	Q. Dr. Bliesner?	01:29	2	that.	01:31
3	A. Yes, sir.	01:29	3	Q. You can't come to a firm conclusion on	01:31
4	Q. I'm talking strictly about this 2008	01:29	4	that?	01:31
5	situation and I want you to stay focused on that	01:29	5	A. That's correct.	01:31
6	for me; okay?	01:29	6	Q. So when you said earlier --	01:31
7	A. Okay.	01:29	7	A. Uh-huh.	01:31
8	Q. You've given sworn testimony here today	01:29	8	Q. -- we know --	01:31
9	that says that this report of the woman who works	01:29	9	A. Yes.	01:31
10	for goldenliving.com is the evidence that allows	01:29	10	Q. -- which is definitive. Am I correct --	01:31
11	you to conclude in your expert witness report that	01:29	11	A. Yes.	01:31
12	you know adulterated Digitek that was part of the	01:29	12	Q. -- that adulterated Digitek was released	01:31
13	recall --	01:29	13	to market, the only thing you have to support that	01:31
14	A. That's --	01:29	14	definitive statement is the 2004 circumstances?	01:31
15	Q. -- made it to market.	01:30	15	A. In the documents I have already	01:31
16	A. That's -- that's a misunderstanding of	01:30	16	reviewed; correct.	01:31
17	what I said. We know that adulterated Digitek	01:30	17	Q. Okay. The only thing you're aware of --	01:31
18	made it to market because of the pharmacist's	01:30	18	no matter what you've reviewed -- is the 2004	01:31
19	discovery here. I have not definitively made a	01:30	19	circumstances; correct?	01:31
20	statement this is a piece of evidence that	01:30	20	A. That's the specific one, yes.	01:32
21	somebody potentially found a double-thick tablet	01:30	21	THE WITNESS: I hate to do this to you.	01:32
22	in the market characterized as a pharmacist.	01:30	22	I need a bathroom break.	01:32
23	Q. So then if I understand what you're	01:30	23	MR. ANDERTON: You certainly may.	01:32
24	doing right now, Dr. Bliesner, you're backing away	01:30	24	THE VIDEOGRAPHER: The time is 1:31 p.m.	01:32
25	from this report.	01:30	25	We're going off the record briefly.	01:32
Page 195			Page 197		
1	A. No, I'm not backing away.	01:30	1	(Short break)	01:40
2	Q. Let's get it clear.	01:30	2	THE VIDEOGRAPHER: The time is 1:42 p.m.	01:40
3	A. Okay.	01:30	3	We're back on the record.	01:40
4	Q. Does this -- do you believe this allows	01:30	4	BY MR. ANDERTON:	01:40
5	to you conclude that --	01:30	5	Q. Dr. Bliesner, you just took a break.	01:40
6	A. With the recalled lot?	01:30	6	Did you speak with Mr. Kerensky during that break?	01:40
7	Q. That part that of -- that -- I'm talking	01:30	7	A. Yes, I did.	01:40
8	only about this situation.	01:30	8	Q. Who called who?	01:40
9	A. Okay.	01:30	9	A. He called me.	01:40
10	Q. Do not --	01:30	10	Q. He did?	01:40
11	A. That situation.	01:30	11	A. Yes.	01:40
12	Q. Do not inject any additional	01:30	12	Q. What did you talk about?	01:40
13	circumstances into your answer; okay?	01:30	13	A. He wanted to ask me how I felt things	01:40
14	A. Okay.	01:30	14	were going, how I felt.	01:41
15	Q. Are we clear on that?	01:30	15	Q. What did you tell him?	01:41
16	A. Yes, sir.	01:30	16	A. I said it's tiring, hard work. I didn't	01:41
17	Q. Are you sure?	01:31	17	get to the point where I said I don't know how you	01:41
18	A. Yes, sir.	01:31	18	people do this for a living, but that's what I was	01:41
19	Q. I'm talking about this report that is in	01:31	19	thinking then he offered some advice.	01:41
20	Defense Exhibit 59A.	01:31	20	Q. What was his advice?	01:41
21	A. Yes.	01:31	21	A. His advice was you realize the report	01:41
22	Q. Do you conclude from this report that	01:31	22	that you wrote is not based on just one or two	01:41
23	adulterated Digitek made it to market?	01:31	23	observations of the adulterated product in the	01:41
24	A. Based on that one report and the fact	01:31	24	market. The basis -- the majority of the basis of	01:41
25	that I may have mischaracterized them as a	01:31	25	the report is this total lack of compliance over	01:41

50 (Pages 194 to 197)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 198			Page 200		
1	the course of years. I said okay.	01:41	1	A. We never use the term infer.	01:43
2	Q. Okay. So he told you to say that?	01:41	2	Q. Okay. You've got --	01:43
3	A. No, he didn't tell me to say that. He	01:41	3	A. In my experience.	01:43
4	said just remember.	01:41	4	Q. So your conclusion in your report which	01:43
5	Q. That's his words though, not yours.	01:41	5	is set forth at page 21, you say it is my opinion	01:43
6	A. No, it's -- yeah it's his words in	01:41	6	to a reasonable degree of certainty that the	01:44
7	general.	01:41	7	systemic failure to implement quality systems and	01:44
8	Q. His words?	01:41	8	to comply with regulations -- with the	01:44
9	A. Yeah. But it is the basis of the	01:41	9	regulations -- resulted in adulterated drug	01:44
10	report. It's true. That's how it was written.	01:41	10	products making it to the marketplace.	01:44
11	Q. But let's call that what it is.	01:41	11	Did I read that correctly?	01:44
12	A. Uh-huh.	01:41	12	A. Yes, you did.	01:44
13	Q. The basis of the report is inferences;	01:41	13	Q. As concerns the product, the Digitek	01:44
14	right?	01:41	14	product that was part of the recall, you don't	01:44
15	A. Inferences?	01:41	15	have any direct proof of that, do you?	01:44
16	Q. Sure.	01:41	16	A. I have proof that they were in	01:44
17	A. How are you defining inferences?	01:41	17	substantial state of discompliance and that those	01:44
18	Q. Well, you have either direct proof --	01:42	18	tablets were manufactured under the quality	01:44
19	A. Uh-huh.	01:42	19	systems or lack of quality systems therein and	01:45
20	Q. -- or inferential proof. You understand	01:42	20	therefore were at risk.	01:45
21	the difference between the two; right?	01:42	21	Q. So what you have proof of is the	01:45
22	A. I do not.	01:42	22	possibility that adulterated Digitek was	01:45
23	Q. Direct proof is something that proves a	01:42	23	manufactured; correct?	01:45
24	proposition to be true. Something follows -- A	01:42	24	A. The likelihood that it could have been	01:45
25	follows from B.	01:42	25	manufactured.	01:45
Page 199			Page 201		
1	A. Okay.	01:42	1	Q. Which is a possibility.	01:45
2	Q. Inferential proof is something that	01:42	2	A. It's probable.	01:45
3	doesn't necessarily prove something is true but	01:42	3	Q. Oh, now you know the difference between	01:45
4	suggests it's true.	01:42	4	possibility and probability.	01:45
5	Do you understand the difference?	01:42	5	A. We talked about it earlier today	01:45
6	A. I think in those terms, yes.	01:42	6	remember?	01:45
7	Q. You know what an inference is; right?	01:42	7	Q. I see. You're a quick study. That's	01:45
8	A. Yes.	01:42	8	good to know.	01:45
9	Q. You know what I mean? Dr. Bliesner, I'm	01:42	9	So in your mind it's probable but still you	01:45
10	a little bit befuddled by your claimed lack of	01:42	10	have no proof; right?	01:45
11	understanding of some of these very basic terms	01:42	11	A. With respect to the recalled lot?	01:45
12	when you spend your life charging people \$500 an	01:42	12	Q. Correct. Lots.	01:45
13	hour or more to do highly technical analytical --	01:42	13	A. Lots.	01:45
14	to provide highly technical analytical services.	01:43	14	Q. Correct. With respect to the recalled	01:45
15	How do you not know the difference off the top of	01:43	15	lots.	01:45
16	your head between direct and inferential?	01:43	16	A. In what I've reviewed, no.	01:45
17	MR. KERENSKY: Objection, form.	01:43	17	Q. All right. And so if you assert as a	01:45
18	BY MR. ANDERTON:	01:43	18	conclusion that adulterated Digitek that was part	01:45
19	Q. You may answer.	01:43	19	of the recalled lots made it to marketplace, the	01:46
20	A. I never been in a deposition with the	01:43	20	only way you do that is by inference; right?	01:46
21	legal implication of some words. It's like the	01:43	21	A. The only way?	01:46
22	definition of "is," is with Clinton.	01:43	22	Q. You don't have any direct proof.	01:46
23	Q. Do you know the difference between	01:43	23	A. For the recalled lots.	01:46
24	direct proof and inferential proof in the ordinary	01:43	24	Q. Correct. And so the only way to reach	01:46
25	course of your FDA GMP consulting career?	01:43	25	that conclusion is by inference; right?	01:46

51 (Pages 198 to 201)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 202	Page 204
<p>1 A. The chronic systemic failure of the 01:46</p> <p>2 quality system and the FDA actions, including two 01:46</p> <p>3 consent decrees and anything like that, if you're 01:46</p> <p>4 defining that as an inference, then the answer 01:46</p> <p>5 would be yes. 01:46</p>	<p>1 the documentation here is that there are numbers 01:48</p> <p>2 of people in the facility that don't even read 01:48</p> <p>3 English. So are they going to document anything 01:48</p> <p>4 bad on a batch record? It brings that into 01:48</p> <p>5 question. 01:48</p>
<p>6 Q. Well, we know you didn't look at any 01:46</p> <p>7 Digitek production records; right? 01:46</p>	<p>6 So, you know, the reality is, is if people 01:49</p> <p>7 make mistakes and they don't read English, are 01:49</p> <p>8 they going to document them on a batch record? 01:49</p>
<p>9 A. That's not necessarily true. 01:46</p> <p>10 Q. You looked at a portion of one batch 01:46</p> <p>11 record; right? 01:46</p>	<p>9 That's a good question and I can't answer it. But 01:49</p> <p>10 it brings into question the batch records doesn't 01:49</p> <p>11 necessarily show you anything definitive. 01:49</p>
<p>12 A. I can't remember specifically. I know I 01:46</p> <p>13 reviewed the ANDA that had batch records in it and 01:46</p> <p>14 I have probably read another document or two. 01:46</p>	<p>12 Q. You can't answer it because you didn't 01:49</p> <p>13 care enough to ask for or even attempt to review 01:49</p> <p>14 the batch records. You can't give any testimony 01:49</p>
<p>15 Q. Okay. There were 152 batches that were 01:46</p> <p>16 recalled. 01:47</p>	<p>15 about the information in the batch records for the 01:49</p> <p>16 recalled batches, can you? 01:49</p>
<p>17 A. Okay. 01:47</p>	<p>17 A. In the batch records? 01:49</p>
<p>18 Q. You didn't review any of the batch 01:47</p> <p>19 records for those 152 batches except for a partial 01:47</p> <p>20 review of the batch where some double-thick 01:47</p> <p>21 tablets were found during manufacturing that were 01:47</p> <p>22 inspected out of the batch before it was 01:47</p> <p>23 released. And the only reason you read that is 01:47</p> <p>24 because you read the investigation report for that 01:47</p> <p>25 batch; correct? 01:47</p>	<p>18 Q. Correct. 01:49</p> <p>19 A. Again, I have to go back. But if I take 01:49</p> <p>20 you at your word, then -- and that from the 01:49</p> <p>21 previous testimony I reviewed a small portion of 01:49</p> <p>22 the batch record, then the answer is I reviewed a 01:49</p> <p>23 small portion of the batch record. 01:49</p> <p>24 Q. From one lot. 01:49</p> <p>25 A. If that's what's in the testimony 01:49</p>
Page 203	Page 205
<p>1 looked at. I tell you that right now. 01:47</p>	<p>1 previously, I'll say yes. 01:49</p>
<p>2 Q. Okay. You gave testimony about it last 01:47</p> <p>3 time. 01:47</p>	<p>2 Q. And as concerns all of the other 151 01:49</p> <p>3 lots at four-plus million tablets each that were 01:49</p>
<p>4 A. Okay. 01:47</p>	<p>4 part of the recall, you can't give any testimony 01:49</p>
<p>5 Q. The record will show what it shows. 01:47</p>	<p>5 about those batch records, can you? 01:50</p>
<p>6 A. Okay. 01:47</p>	<p>6 A. Specifically the batch records? 01:50</p>
<p>7 Q. But you certainly didn't review any of 01:47</p> <p>8 the batch records beyond that single batch with 01:47</p> <p>9 respect to the recalled batches; correct? 01:47</p>	<p>7 Q. Yeah. 01:50</p> <p>8 A. No. 01:50</p> <p>9 Q. So you can't say anything one way or the 01:50</p>
<p>10 A. I don't believe so. 01:47</p>	<p>10 other about whether they're accurate not accurate, 01:50</p>
<p>11 Q. Okay. So you conducted a paper audit? 01:47</p>	<p>11 whether there appears to be some sort of mistake 01:50</p>
<p>12 A. Yes, sir. 01:47</p>	<p>12 in them, you can't give any testimony about them, 01:50</p>
<p>13 Q. Without reviewing production records? 01:47</p>	<p>13 can you? 01:50</p>
<p>14 A. Yes. 01:47</p>	<p>14 A. That's not true. If you have a 01:50</p>
<p>15 Q. And from that paper audit of 01:48</p> <p>16 non-production records, primarily FDA regulatory 01:48</p> <p>17 documentation, you conclude there is a possibility 01:48</p> <p>18 that adulterated Digitek was produced and 01:48</p> <p>19 therefore there is a possibility that adulterated 01:48</p> <p>20 Digitek was released; correct? 01:48</p>	<p>15 substantial quality system failures as documented 01:50</p> <p>16 by the FDA, you're going to have problems. 01:50</p> <p>17 Q. How would the FDA determine whether a 01:50</p> <p>18 quality system deficiency impacted a specific 01:50</p> <p>19 product? How would the FDA do it? 01:50</p> <p>20 A. How would they determine? 01:50</p>
<p>21 A. No, it probably was released to market. 01:48</p>	<p>21 Q. Yeah. 01:50</p>
<p>22 If you go back and you look at the FDA reports and 01:48</p> <p>23 the findings, first of all, batch record is not 01:48</p>	<p>22 A. They don't have to. They see quality 01:50</p> <p>23 system failure, they write you up. 01:50</p>
<p>24 the end all be all for documenting whether things 01:48</p>	<p>24 Q. They write you up. 01:50</p>
<p>25 are good or bad. In fact as we know from reading 01:48</p>	<p>25 How would they determine whether a specific 01:50</p>

52 (Pages 202 to 205)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 206			Page 208		
1	product was impacted?	01:50	1	FDA practice that ought to be right down the	01:53
2	A. If it would not fall under the GMPs and	01:51	2	middle of that expertise. I don't know why you	01:53
3	there was doubt, that's how they determine.	01:51	3	don't want to answer it, but -- I know exactly why	01:53
4	Q. That would create a possibility that	01:51	4	you don't want to answer it but I'm going to keep	01:53
5	some deficiency impacted some product; right?	01:51	5	asking it until you do.	01:53
6	A. Say that again, or should I have him	01:51	6	MR. KERENSKY: Objection, form.	01:53
7	read it back? Because I don't know if I	01:51	7	BY MR. ANDERTON:	01:53
8	understand that.	01:51	8	Q. Okay. How would the FDA -- let's	01:53
9	MR. ANDERTON: Please, Phil, read it	01:51	9	assume, Dr. Bliesner, that the FDA was doing an	01:53
10	back.	01:51	10	inspection and uncovered a GMP practice that they	01:53
11	(Whereupon, the testimony was read	01:51	11	believed was deficient.	01:53
12	back by the court reporter, as recorded above)	01:51	12	A. Okay.	01:53
13	THE WITNESS: Possibility that some	01:51	13	Q. That happens; right?	01:53
14	deficiency could potentially impact. The FDA	01:51	14	A. Yes, it does.	01:53
15	does not need the probable definition. All	01:51	15	Q. That's what you charge your clients to	01:53
16	they have to go in and see that there are	01:51	16	assess; right?	01:53
17	deficiencies with respect to the quality	01:51	17	A. Yes.	01:53
18	systems. They do whatever they want and take	01:51	18	Q. If the FDA wanted to determine whether	01:53
19	action on it.	01:51	19	that GMP deficiency impacted a particular product,	01:53
20	BY MR. ANDERTON:	01:51	20	how would they do that?	01:53
21	Q. I understand that.	01:51	21	A. They may or may not start looking at all	01:54
22	A. Uh-huh.	01:51	22	of the quality systems that are in there. I'm	01:54
23	Q. I asked you a question and I would like	01:51	23	just telling you how they do it. They could stop	01:54
24	you to answer now. How would the FDA determine	01:51	24	when they see significant deficiencies and there	01:54
25	whether a specific GMP systems deficiency impacted	01:51	25	is doubt in their mind they just stop. That's	01:54
Page 207			Page 209		
1	a specific problem? I'm sorry a specific	01:52	1	what they do.	01:54
2	product.	01:52	2	Q. Why don't you want to ask answer that	01:54
3	A. Well, I don't work for the FDA and I'm	01:52	3	question? I know the answer. I know why you	01:54
4	not going to speak for the FDA, but if they	01:52	4	don't want to.	01:54
5	find -- go back look at the EIRs and see that	01:52	5	A. Well, what's the answer?	01:54
6	there are all kinds of problems with respect to	01:52	6	Q. Dr. Bliesner, how would the FDA	01:54
7	manufacturing records and lack of manufacturing	01:52	7	determine whether a specific GMP deficiency	01:54
8	records, validated processes and things like	01:52	8	impacted a specific product? What would they do?	01:54
9	that. So that's what they do.	01:52	9	MR. KERENSKY: Objection, form, prior to	01:54
10	They put -- if the question as to the	01:52	10	the word "how?"	01:54
11	integrity of the manufactured product, then, you	01:52	11	BY MR. ANDERTON:	01:54
12	know, they take action.	01:52	12	Q. You may answer.	01:54
13	Q. What question were you just answering?	01:52	13	A. Again, please.	01:54
14	I move to strike that as completely	01:52	14	Q. I'll ask it again.	01:54
15	non-responsive.	01:52	15	A. Okay.	01:54
16	Were you talking about Activis or their	01:52	16	Q. And we're going to set up the whole	01:54
17	records somehow?	01:52	17	situation again; okay?	01:54
18	A. I'm talking about the records that the	01:52	18	A. Okay.	01:54
19	FDA reviewed and their systems and places that	01:52	19	Q. So that I understand -- so that I know	01:54
20	will show up on the establishment inspection	01:52	20	you're clear in what we're talking about.	01:54
21	report.	01:52	21	A. Okay.	01:55
22	Q. Are you an expert in GMP compliance or	01:52	22	Q. The FDA can -- the FDA conducts	01:55
23	not?	01:53	23	inspections; right?	01:55
24	A. Am I am, sir.	01:53	24	A. That's correct.	01:55
25	Q. Okay. I'm asking you a question about	01:53	25	Q. If they notice a condition which they	01:55

53 (Pages 206 to 209)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 210		Page 212	
1	believe is a violation of good manufacturing practices -- 01:55	1	not. Electronic data are traditionally not. 01:57
2	A. Yes. 01:55	2	Q. But the data is? 01:57
3	Q. -- they make a note or a record of that 01:55	3	A. The final results. 01:57
4	somehow; correct? 01:55	4	Q. The data that the chromatogram generates 01:57
5	A. Yes, they do. 01:55	5	or reflects is part of the batch record; right? 01:57
6	Q. If that GMP violation or deficiency 01:55	6	A. We're talking about -- I'm -- please 01:57
7	related to a specific -- or to a quality system, 01:55	7	don't take this wrong. Your understanding of raw 01:57
8	they'd make a note of that; right? 01:55	8	data as opposed to a result, they're different 01:57
9	A. Yes, they do 01:55	9	things. 01:57
10	Q. And they notify the company of that 01:55	10	Q. Okay. 01:57
11	quality system GMP deficiency; right? 01:55	11	A. Okay. 01:57
12	A. Typically, yes. 01:55	12	Q. But the bottom line is the FDA if they 01:57
13	Q. All right. In the ordinary course, 01:55	13	wanted to determine whether a quality systems 01:57
14	that's what they would do? 01:55	14	deficiency impacted a specific product, they'd go 01:57
15	A. Yes. 01:55	15	look at the records, some portion of the records 01:57
16	Q. They are not in the business of ignoring 01:55	16	for that specific product, wouldn't they? 01:57
17	or overlooking deficiencies that they find, are 01:55	17	A. They'll look at the records that 01:57
18	they? 01:55	18	indicate where the difficulties are. For 01:57
19	A. No, not at all. Not at all. 01:55	19	instance, if they think there's problems with an 01:58
20	Q. I don't know why you felt compelled to 01:55	20	analytical method, they'll go in and they'll start 01:58
21	say typically in that situation. But Dr. Bliesner 01:55	21	pulling up chromatographic data, look at the 01:58
22	in that situation, if the FDA found a GMP 01:55	22	results that come out there, look at peaks, look 01:58
23	deficiency in the quality systems and wanted then 01:56	23	how they're innovated, pull up the development 01:58
24	to inquire or determine whether that deficiency 01:56	24	report, pull up the validation report, things like 01:58
25		25	that. 01:58
Page 211		Page 213	
1	had any impact on a specific product -- 01:56	1	If they think there are discrepancies with 01:58
2	A. Yes. 01:56	2	respect to improper documentation or execution of 01:58
3	Q. -- what would they do? 01:56	3	batch records, then they can pull the batch 01:58
4	MR. KERENSKY: Form. Objection, form. 01:56	4	records and take a look at it. 01:58
5	THE WITNESS: It depends, you know, what 01:56	5	Q. So what you've just described is a 01:58
6	deficiency it is in quality systems; all 01:56	6	process whereby the FDA would look at some 01:58
7	right? For instance, let's say they go in the 01:56	7	variation, some component -- some or all of the 01:58
8	laboratory, they pull up some data, they look 01:56	8	production records for the product. The only way 01:58
9	at chromatograms -- 01:56	9	they could conclude that a quality system 01:58
10	BY MR. ANDERTON: 01:56	10	deficiency actually impacted a specific product is 01:58
11	Q. Stop. Data and chromatograms for what? 01:56	11	to go look at the records that relate to that 01:58
12	For the product? 01:56	12	product; correct? 01:58
13	A. Yes. 01:56	13	A. The raw data in the records, the reports 01:58
14	Q. Sounds to me like they're reviewing 01:56	14	that come out of it. 01:58
15	production records for that product. 01:56	15	Q. Right. 01:58
16	A. They will review batch records as well. 01:56	16	A. That's correct. 01:58
17	Q. Okay. 01:56	17	Q. Couldn't reach that to product -- strike 01:58
18	A. Chromatographic data and reports aren't 01:56	18	that. 01:58
19	necessarily -- you know, they're included with the 01:56	19	MR. ANDERTON: We're going to change the 01:59
20	reported results, included in batch record, but 01:57	20	tape. 01:59
21	the raw data and the stuff is not. 01:57	21	THE VIDEOGRAPHER: It's 2:01 p.m. We're 01:59
22	Q. You don't think that's part of the batch 01:57	22	going off the record. 01:59
23	record? 01:57	23	(Short break) 02:00
24	A. The data is reported results, but 01:57	24	THE VIDEOGRAPHER: The time is 2:03 p.m. 02:00
25	chromatograms in my experience traditionally are 01:57	25	We are back on record. This is the beginning 02:02

54 (Pages 210 to 213)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 214			Page 216		
1	of tape six.	02:02	1	compliance I would say, yes.	02:06
2	BY MR. ANDERTON:	02:02	2	Q. For GMP issues?	02:06
3	Q. Dr. Bliesner, in the paper audit that	02:02	3	A. Yes.	02:06
4	you conducted, you placed heavy emphasis on the	02:02	4	Q. Look at page 5.	02:06
5	FDA regulatory documents, didn't you?	02:02	5	A. Uh-huh.	02:06
6	A. Yes, sir, I did.	02:02	6	Q. Observation seven. Do you see that?	02:06
7	Q. They carry great weight with you, don't	02:02	7	A. Yes.	02:06
8	they?	02:02	8	Q. That is an observation that relates to	02:06
9	A. Yes, they do.	02:02	9	the bulk stability hold times studies.	02:06
10	Q. Dr. Bliesner, I'm handing you a document	02:02	10	Do you see that?	02:06
11	that has been marked as -- previously marked by	02:03	11	A. Yes. Just, if I may, I may not --	02:06
12	the Plaintiffs as Exhibit 68. As you can see by	02:03	12	Q. Dr. Bliesner.	02:06
13	the sticker, they used it in a deposition on	02:03	13	A. -- have seen some of this stuff because	02:07
14	December 9, 2009.	02:03	14	a lot of the copies we had were redacted, just so	02:07
15	A. Okay.	02:03	15	you know.	02:07
16	Q. Will you just look at that document for	02:03	16	Q. Well, nothing like hiding something from	02:07
17	a moment? I don't want you to read it.	02:03	17	yourself.	02:07
18	A. Okay.	02:03	18	Well, let's just do it. You see observation	02:08
19	Q. I just want you to skim through it and	02:03	19	five on there or observation seven there on page	02:08
20	satisfy yourself of what it is.	02:03	20	5?	02:08
21	MR. KERENSKY: I can't hear what	02:03	21	A. Yes.	02:08
22	exhibit. I'm sorry.	02:03	22	Q. All right. Do you remember the	02:08
23	MR. ANDERTON: 68, Mike.	02:03	23	testimony that you gave on January 25th about bulk	02:08
24	MR. KERENSKY: Okay.	02:04	24	stability hold time studies?	02:08
25	MR. ANDERTON: And it's Plaintiffs'	02:04	25	A. No.	02:08
Page 215			Page 217		
1	Exhibit 68. You got that part; right?	02:04	1	Q. You don't; okay.	02:08
2	MR. KERENSKY: I did not. Thank you.	02:04	2	Do you remember telling Mr. Moriarty that you	02:08
3	That's why I couldn't find it.	02:04	3	questioned whether the Activis -- whether the	02:08
4	MR. ANDERTON: Right. I'm here to help,	02:04	4	Digitek process validation -- whether the FDA had	02:08
5	Mike.	02:04	5	any issues with the Digitek process validation	02:08
6	BY MR. ANDERTON:	02:05	6	because you had seen a reference to bulk stability	02:08
7	Q. Have you seen that document before?	02:05	7	hold times in this 483, and you thought that that	02:08
8	A. I believe I have seen it either as part	02:05	8	related to process validation?	02:08
9	of an EIR or stand-alone or both.	02:05	9	A. I don't recall that, that statement.	02:08
10	Q. I'll take that as a yes. It's a 2006	02:05	10	Q. Do you -- do you --	02:08
11	483 -- it's a 483 form issued in August of 2006 by	02:05	11	A. I --	02:08
12	the FDA, following an inspection of the Activis	02:05	12	Q. -- stand by that testimony? Does bulk	02:08
13	Totowa Little Falls facility; correct?	02:05	13	stability hold time studies have anything to do	02:09
14	A. Yes.	02:05	14	with process validation?	02:09
15	Q. Dates of inspection July 10, 2006, to	02:05	15	A. I'm not clear what they're meaning by	02:09
16	August 10, 2006; correct?	02:05	16	bulk stability hold here.	02:09
17	A. Correct.	02:05	17	Q. You gave the testimony, Dr. Bliesner, I	02:09
18	Q. All right. And are you familiar enough	02:05	18	didn't. I'm asking you a question. Does bulk	02:09
19	with the document, Dr. Bliesner, to -- to say that	02:05	19	stability hold time studies have anything to do	02:09
20	this document relates to various GMP circumstances	02:06	20	with process validation?	02:09
21	of Activis Totowa, as reflected in this inspection	02:06	21	MR. KERENSKY: Objection, form.	02:09
22	report?	02:06	22	MR. ANDERTON: What's wrong with that	02:09
23	A. GMP circumstances?	02:06	23	form, Mike? I would like to correct it if you	02:09
24	Q. Yeah.	02:06	24	will allow.	02:09
25	A. Failure of compliance? Failure of	02:06	25	MR. KERENSKY: It's a sidebar. You gave	02:09

55 (Pages 214 to 217)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 218			Page 220		
1	him the answer, I didn't. I doubt you will.	02:09	1	Q. It does not?	02:11
2	MR. ANDERTON: Say that one more time.	02:09	2	A. Yes, uh-huh.	02:11
3	What's wrong with the form?	02:09	3	Q. Okay. Are you aware of any other	02:11
4	MR. KERENSKY: It is a sidebar of you	02:09	4	evidence that you have reviewed that calls into	02:11
5	gave the testimony, I didn't. That kind of	02:09	5	question the validity of the Digitek process	02:11
6	comment prior to the question is objectionable	02:09	6	validation?	02:12
7	where I practice law.	02:09	7	A. Yes.	02:12
8	MR. ANDERTON: Oh, okay.	02:09	8	Q. What?	02:12
9	BY MR. ANDERTON:	02:09	9	A. There were internal studies and	02:12
10	Q. So my question, Dr. Bliesner, absent any	02:09	10	investigations with respect to process validation,	02:12
11	preface comment is do bulk stability hold time	02:10	11	blend uniformity.	02:12
12	studies have anything to do with process	02:10	12	Q. Okay. So there were investigations --	02:12
13	validation?	02:10	13	A. I misspoke. With respect to process	02:12
14	A. They can, yes.	02:10	14	validation, no.	02:12
15	Q. As you read this observation 7, does it?	02:10	15	Q. Okay.	02:12
16	A. With respect to these products.	02:10	16	A. With respect to blend uniformity. I'm	02:12
17	Q. It does?	02:10	17	sorry.	02:12
18	A. Bulk stability -- we're talking about	02:10	18	MR. ANDERTON: Phil, would you please	02:12
19	final blend or are we talking about manufactured	02:10	19	read back my question very slowly and very	02:12
20	tablets? In this particular case it's	02:10	20	deliberately. Dr. Bliesner, would you please	02:12
21	particularly clear.	02:10	21	answer my question?	02:12
22	Q. Okay. What's really clear, however --	02:10	22	THE WITNESS: Yes, sir.	02:13
23	A. Uh-huh.	02:10	23	(Whereupon, the testimony was read	02:13
24	Q. -- is that Digitek --	02:10	24	back by the court reporter, as recorded above)	02:13
25	A. Uh-huh.	02:10	25	THE WITNESS: I have to go back through	02:13

Page 219			Page 221		
1	Q. -- is not mentioned as one of the	02:10	1	my report and take a look.	02:13
2	products that the FDA cited in this observation;	02:10	2	BY MR. ANDERTON:	02:13
3	correct?	02:10	3	Q. You're really desperate not to do	02:13
4	A. In the copy I'm looking at, yes.	02:10	4	anything you can to undermine Activis, aren't	02:13
5	Q. Do you think that I'm looking at a	02:10	5	you? You already testified about this last time,	02:13
6	different copy?	02:10	6	Dr. Bliesner, and you identified only the bulk	02:13
7	A. I was specifically told don't look at	02:10	7	stability hold time studies.	02:13
8	anything that has to do with any other product	02:10	8	MR. KERENSKY: Form.	02:13
9	other than Digitek. So if I had this copy with no	02:10	9	BY MR. ANDERTON:	02:13
10	Digitek on there, I'm pretty sure I would not have	02:11	10	Q. Now you have reviewed your report	02:13
11	made a comment on it.	02:11	11	forwards and backwards many times today and many	02:13
12	Q. Well, Dr. Bliesner, again, the last time	02:11	12	times last time. Are you aware --	02:13
13	you were here --	02:11	13	MR. KERENSKY: The witness is allowed to	02:13
14	A. Okay.	02:11	14	review his report as much as he can to give	02:13
15	Q. -- you identified this observation as a	02:11	15	accurate testimony, and I think you probably	02:13
16	reason why you questioned the validity of the	02:11	16	know that.	02:13
17	Digitek process validation. I'm sorry. Let me	02:11	17	MR. ANDERTON: I do know that. I also	02:13
18	strike that.	02:11	18	know that he's now contradicting his own prior	02:13
19	You cited to this observation as a basis for	02:11	19	testimony whether he realizes it or not. So	02:13
20	wondering whether the FDA questioned the process	02:11	20	if he wants to go back through his report, he	02:13
21	validation for Digitek. So does this have	02:11	21	certainly may.	02:13
22	anything to do with the process validation for	02:11	22	BY MR. ANDERTON:	02:14
23	Digitek?	02:11	23	Q. But my question is are you aware of any	02:14
24	A. In this particular case, it does not	02:11	24	other evidence that calls into question the	02:14
25	look so.	02:11	25	validity of the process validation for Digitek?	02:14

56 (Pages 218 to 221)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 222			Page 224		
1	A. Any other information? Again, I need to	02:14	1	validation?	02:16
2	go back through my report and see what references	02:14	2	A. Yes, and that's when I told you I got	02:16
3	I reviewed with respect to process validation.	02:14	3	that document last night and I didn't review it.	02:16
4	Q. You didn't say anything about the	02:14	4	Q. Okay.	02:16
5	Digitek process validation in your report, not a	02:14	5	A. That's -- I got it late.	02:16
6	word about it being unreliable, and you testified	02:14	6	Q. Well, Dr. Bliesner, you've already given	02:16
7	last time that you didn't review the process	02:14	7	this testimony last time. With respect to	02:16
8	validations.	02:14	8	observation 7 --	02:16
9	Out of a desperate attempt to create some	02:14	9	A. Uh-huh.	02:16
10	negative inference with respect to Activis, you	02:14	10	Q. -- on the 2006, 483 --	02:16
11	tried to identify this bulk stability hold time	02:14	11	A. Uh-huh.	02:16
12	reference in this 483 as evidence.	02:14	12	Q. -- does that have anything to do with	02:16
13	MR. KERENSKY: Is that a question or a	02:14	13	the Digitek process validation?	02:16
14	speech? In either case, I object as to form.	02:14	14	A. No, this is just related to these	02:16
15	BY MR. ANDERTON:	02:14	15	products here.	02:16
16	Q. So, Dr. Bliesner, what -- if you didn't	02:14	16	Q. Okay.	02:16
17	say anything in your report about process	02:14	17	A. According to this document.	02:16
18	validation, what would you be looking for?	02:15	18	Q. Can't resist, can you?	02:16
19	MR. KERENSKY: Objection, form. Assumes	02:15	19	A. Resist what? I'm sorry.	02:16
20	facts not in evidence.	02:15	20	Q. Your -- your solicited, gratuitous,	02:16
21	BY MR. ANDERTON:	02:15	21	editorial comments at the end of every answer to	02:16
22	Q. You may -- you may answer.	02:15	22	make sure you follow Plaintiffs' counsels'	02:16
23	A. Ask it again, please.	02:15	23	directive to keep the door open.	02:16
24	Q. If you didn't say anything about the	02:15	24	MR. KERENSKY: Objection to form. You	02:16
25	Digitek process validation in your report --	02:15	25	know, speaking objections go for both sides of	02:16

Page 223			Page 225		
1	A. That's correct.	02:15	1	the table.	02:16
2	Q. -- what would you be looking for?	02:15	2	MR. ANDERTON: I'm sorry, Mike. I'm not	02:16
3	A. If I didn't?	02:15	3	sure I understand.	02:17
4	Q. Yeah.	02:15	4	MR. KERENSKY: You know when you give a	02:17
5	A. Chances are I didn't have documents that	02:15	5	speech like that, admonishing the witness and	02:17
6	would support that.	02:15	6	trying to intimidate the witness, that's just	02:17
7	Q. So --	02:15	7	like a speaking objection, trying to coach the	02:17
8	A. Chances are.	02:15	8	witness.	02:17
9	Q. So you wouldn't have any evidence?	02:15	9	MR. ANDERTON: I'm merely trying to get	02:17
10	A. None of the documents were not given to	02:15	10	him to answer the questions that are asked of	02:17
11	me to review.	02:15	11	him. We've been down this road all day.	02:17
12	Q. Oh, you assume they're out there, you	02:15	12	MR. KERENSKY: I think you should stick	02:17
13	just didn't get them?	02:15	13	to questions and not speeches.	02:17
14	A. I know they're out there.	02:15	14	MR. ANDERTON: Okay.	02:17
15	Q. You know there's documents out there	02:15	15	MR. KERENSKY: Save speeches for the	02:17
16	that call the process validation into question?	02:15	16	judge and the jury would be my recommendation.	02:17
17	A. No, I don't have a question on the	02:15	17	MR. ANDERTON: I appreciate your	02:17
18	documents with respect to process validation.	02:15	18	recommendation, Mike.	02:17
19	Q. And by the way, you most certainly were	02:15	19	MR. KERENSKY: Thank you.	02:17
20	given them if you reviewed all of Plaintiffs'	02:15	20	BY MR. ANDERTON:	02:17
21	exhibits.	02:15	21	Q. So Dr. Bliesner, I'm now going to hand	02:17
22	A. I did not review all of Plaintiffs'	02:15	22	you a document that has been marked as --	02:17
23	Exhibits in detail.	02:15	23	previously marked as Plaintiffs' Exhibit 25. Take	02:17
24	Q. Didn't you tell me that last night from	02:15	24	a moment and look at that document, please.	02:17
25	Plaintiffs' counsel you received process	02:16	25	Actually, may I see that back?	02:18

57 (Pages 222 to 225)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 226			Page 228		
1	A. Sure.	02:18	1	directly to the 483 that we discussed a moment	02:28
2	Q. I may have given you the wrong	02:18	2	ago, that is Plaintiffs' Exhibit 68; correct?	02:28
3	document. No.	02:18	3	A. I'm sorry. Say that again. I was	02:28
4	THE WITNESS: This is going to look like	02:18	4	looking at the contents.	02:28
5	delaying tactics, but I've got to go to the	02:18	5	Q. This warning letter --	02:28
6	bathroom.	02:18	6	A. Yes.	02:28
7	MR. ANDERTON: Okay.	02:18	7	Q. -- relates directly to the 483 that is	02:28
8	THE VIDEOGRAPHER: The time is 2:19 p.m.	02:18	8	Plaintiffs' Exhibit 68; correct?	02:28
9	We're going off the record.	02:18	9	A. I don't know. The warning letter? Yes.	02:28
10	(Short break)	02:25	10	Q. Okay. So you have an inspection in July	02:28
11	THE VIDEOGRAPHER: The time is 2:27 p.m.	02:25	11	and August of 2006 resulting a 483; right?	02:28
12	We are back on the record.	02:25	12	A. Uh-huh.	02:28
13	MR. ANDERTON: We're going to make a	02:25	13	Q. You have to say or no?	02:28
14	record of that before we close down, Mike, if	02:25	14	A. Yes, I'm sorry.	02:29
15	that's all right.	02:25	15	Q. About six months later, a warning letter	02:29
16	MR. KERENSKY: Yes, that's fine.	02:25	16	was issued by the FDA; right?	02:29
17	BY MR. ANDERTON:	02:25	17	A. That's correct, uh-huh.	02:29
18	Q. Dr. Bliesner, I'm going to hand you what	02:25	18	Q. Okay. All right. Dr. Bliesner, I'm	02:29
19	has previously been marked as Plaintiffs' Exhibit	02:25	19	handing you a document that has been marked as	02:29
20	25.	02:25	20	Plaintiffs' Exhibit 171.	02:29
21	A. Okay.	02:25	21	A. Okay.	02:29
22	Q. Have you seen that document before?	02:25	22	Q. And this document was actually marked	02:29
23	A. I believe I have, but there was an	02:26	23	twice but go to page 44 of your report, please.	02:29
24	original one and there was a revised one, and I'm	02:26	24	A. I'm sorry 44 of the?	02:30
25	not sure which one I had the ability to review.	02:26	25	Q. Of your report.	02:30
Page 227			Page 229		
1	Q. You don't know whether you got to review	02:26	1	A. My report; okay. A little punchy.	02:30
2	the revised warning letter? If you don't know	02:26	2	Sorry.	02:30
3	that, how do you know there was one?	02:26	3	Q. Do you see reference A29?	02:30
4	A. There was -- if I recall, correctly	02:26	4	A. I do.	02:30
5	there was a warning letter and then there was a	02:27	5	Q. Is your reference A29 -- notwithstanding	02:30
6	revised warning letter.	02:27	6	the discrepancy in the exhibit numbers as I told	02:30
7	Q. Yeah, what's this document say on top?	02:27	7	you, this document was marked twice at two	02:30
8	A. This one is the revised warning letter.	02:27	8	depositions, one says 158, one says 171.	02:30
9	I'm not sure which one I looked at.	02:27	9	Nevertheless, please look at your reference A29	02:30
10	Q. Did you only look at one of those two?	02:27	10	and tell me whether that is the same thing as what	02:30
11	A. I don't recall. Let's see.	02:27	11	you've now been given, which is in front of you as	02:30
12	Q. All right. Dr. Bliesner, look at page	02:27	12	Exhibit 171.	02:30
13	41 of your report.	02:27	13	A. A29. And your statement again was?	02:31
14	A. Okay. Okay. And that would be it?	02:27	14	Q. Is that the same as your reference A29?	02:31
15	Q. Have you seen that document before?	02:27	15	A. Let me double check. My A29 doesn't	02:31
16	A. Yes.	02:27	16	have the cover letter.	02:31
17	Q. In fact you reviewed it preparing your	02:27	17	Q. Doesn't have the cover letter, but	02:31
18	report; right?	02:28	18	otherwise is it the exact same EIR?	02:31
19	A. Yes.	02:28	19	A. It is, but there's redactions	02:32
20	Q. And according to your description of	02:28	20	Q. In which one?	02:32
21	content, I'll use your words not mine, this	02:28	21	A. This one you just handed me as opposed	02:32
22	warning letter -- this is -- starts on page 41 and	02:28	22	to this one.	02:32
23	continues on to page 42.	02:28	23	Q. Okay.	02:32
24	A. Yes.	02:28	24	A. So there --	02:32
25	Q. This warning letter is -- relates	02:28	25	Q. That's fine.	02:32

58 (Pages 226 to 229)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 230			Page 232		
1	A. Uh-huh.	02:32	1	letter that was issued February 1, 2007, which was	02:35
2	Q. Now, let's look at -- and again working	02:32	2	issued after an inspection in July and August of	02:35
3	from the one I handed you as 171.	02:32	3	2006; correct?	02:35
4	A. Okay.	02:32	4	A. The original inspection July, August,	02:35
5	Q. Turn to page 11.	02:32	5	2006, yes. Follow-up inspection off the issued	02:35
6	A. 11 of 40?	02:33	6	warning letter September, yes.	02:35
7	Q. Correct.	02:33	7	Q. Okay.	02:35
8	A. Okay.	02:33	8	A. Uh-huh.	02:35
9	Q. Actually, let's go to page 2 of 40.	02:33	9	Q. So the items that are set forth in the	02:35
10	Do you see the summary?	02:33	10	warning letter --	02:35
11	A. Yes, sir.	02:33	11	A. Uh-huh.	02:35
12	Q. The first sentence of the summary	02:33	12	Q. -- of February 1, 2007 --	02:35
13	indicates that this inspection was conducted as a	02:33	13	A. Uh-huh.	02:35
14	follow-up to warning letter 07-NWJ-06.	02:33	14	Q. -- are the items that are also set forth	02:35
15	A. Okay.	02:33	15	in the 483 issued in August of 2006 following the	02:35
16	Q. Is that the same warning letter that is	02:33	16	inspection; right?	02:36
17	Plaintiffs' Exhibit 25 that you just looked at a	02:33	17	A. Correct.	02:36
18	moment ago?	02:33	18	Q. Now -- now we can go to -- well,	02:36
19	A. 25 you said; correct?	02:33	19	actually go to page 5 of 60.	02:36
20	Q. Uh-huh.	02:34	20	A. 5 of 60?	02:36
21	A. Okay. It does appear to be, yes.	02:34	21	Q. On the EIR for the 2007 inspection.	02:36
22	Q. Okay. Is it or not?	02:34	22	A. Okay.	02:36
23	A. Yes, according to the code, yeah.	02:34	23	Q. Do you see the first paragraph there?	02:36
24	Q. Okay. And -- and so you know from your	02:34	24	A. The compliance status?	02:36
25	experience that when a warning letter is issued	02:34	25	Q. Yes.	02:36
Page 231			Page 233		
1	oftentimes -- maybe not perhaps all of the time --	02:34	1	A. Yes.	02:36
2	the FDA will come back and ask to see verification	02:34	2	Q. What's a compliance hold?	02:36
3	of remedial activities and corrective activities	02:34	3	A. A compliance hold is where they may put	02:36
4	performed by the manufacturer to the items set	02:34	4	a hold on manufacturing and shipping of certain	02:36
5	forth in the warning letter; correct?	02:34	5	products, depending on the impact in the EIR.	02:36
6	A. That is common, yes.	02:34	6	Q. Okay. And might they also put a hold on	02:36
7	Q. Okay. You've assisted clients with --	02:34	7	new product approvals?	02:37
8	with exactly those types of inspections, haven't	02:34	8	A. Not necessarily.	02:37
9	you?	02:34	9	Q. Might they?	02:37
10	A. Inspections or the remediation.	02:34	10	A. They could.	02:37
11	Q. Well, remediation and then the follow-up	02:34	11	Q. Could?	02:37
12	inspections.	02:34	12	A. Uh-huh.	02:37
13	A. Yes.	02:34	13	Q. Is it -- is it uncommon for a	02:37
14	Q. You've assisted with both.	02:34	14	manufacturer who is -- who is, to use the term	02:37
15	A. Yes.	02:34	15	quote "under" a warning letter, to have new	02:37
16	Q. Right?	02:34	16	product approvals stayed until the warning letter	02:37
17	A. Yes.	02:34	17	is lifted?	02:37
18	Q. Okay. So this inspection then that was	02:34	18	MR. ANDERTON: Phil, would you read it	02:38
19	conducted in 2007 --	02:35	19	back, please?	02:38
20	A. Okay.	02:35	20	THE VIDEOGRAPHER: The time is 2:40 p.m	02:38
21	Q. -- from September 5 to September 28 --	02:35	21	going off the record.	02:38
22	do I have those dates right?	02:35	22	(Short break)	02:40
23	A. Yes.	02:35	23	THE VIDEOGRAPHER: The time is 2:42 p.m.	02:40
24	Q. It was a follow-up inspection to the	02:35	24	We're back on the record.	02:40
25	warning letter that was -- the revised warning	02:35	25	MR. ANDERTON: Phil, would you please	02:40

59 (Pages 230 to 233)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 234			Page 236		
1	slowly read back that question?	02:40	1	A. Okay. All right. Yes. It would	02:43
2	(Whereupon, the testimony was read	02:40	2	reflect -- you can go back and at the 483s, it	02:43
3	back by the court reporter, as recorded above)	02:40	3	would be there.	02:43
4	THE WITNESS: In my experience, companies	02:40	4	Q. So my question is, Dr. Bliesner, after	02:43
5	that are under regulatory action like a	02:40	5	the inspection that is reflected in the EIR, that	02:43
6	warning letter or consent decree in my	02:40	6	is Plaintiffs' or, yeah, Plaintiffs' Exhibit 171,	02:43
7	experience is that they are allowed to	02:41	7	a 483 was issued; correct?	02:43
8	continue new product development and have	02:41	8	A. 171. Okay. I just want to make sure	02:44
9	regular inspections by the FDA as it	02:41	9	because we've got several different layers here.	02:44
10	progresses.	02:41	10	Yes.	02:44
11	BY MR. ANDERTON:	02:41	11	Q. All right. You say so in your report.	02:44
12	Q. Okay. But a compliance hold is -- is	02:41	12	A. Yes, yes. I'm just confused because we	02:44
13	some restriction on the company's activities?	02:41	13	have different versions and different numbers and	02:44
14	A. Yes.	02:41	14	stuff. I wanted to be sure.	02:44
15	Q. Defined by the circumstances, I	02:41	15	Q. Okay. And in that 483, there were three	02:44
16	suppose.	02:41	16	observations; right?	02:44
17	A. Yes.	02:41	17	A. Yes, according to this.	02:44
18	Q. Now, after this -- well, let's go to	02:41	18	Q. You lay those out on page 44 of your	02:44
19	page 11 of 40.	02:41	19	report and they are also set forth in this EIR;	02:44
20	Do you see the inspection coverage heading?	02:41	20	isn't that right?	02:44
21	A. Yes.	02:41	21	A. Yes.	02:44
22	Q. According to that page, the quality	02:41	22	Q. And in among those three observations,	02:44
23	production laboratory control materials and	02:41	23	none of them have anything do with Digitek,	02:44
24	facilities and equipment systems were covered	02:41	24	correct?	02:44
25	during this inspection. That is five of the six	02:41	25	A. The general observations and supporting	02:46
Page 235			Page 237		
1	systems typically inspected by the FDA; correct?	02:42	1	data, the general observations indicate there is	02:46
2	A. Yes.	02:42	2	nothing referred back to Digitek.	02:46
3	Q. The only one not covered is packaging.	02:42	3	Q. Okay.	02:46
4	A. Packaging and labeling.	02:42	4	A. Uh-huh.	02:46
5	Q. Sorry packaging and labeling. And you	02:42	5	Q. And do you know that the outcome of this	02:46
6	know packaging and labeling was in a different	02:42	6	inspection was what is referred to as V -- as in	02:46
7	facility from all of these other operations;	02:42	7	victory -- VAI?	02:46
8	right?	02:42	8	A. Voluntary action indicated?	02:46
9	A. I didn't know if it was exclusive, but I	02:42	9	Q. Yes.	02:46
10	know there was packaging and labeling going on in	02:42	10	A. I don't recall.	02:46
11	another facility.	02:42	11	Q. Do you have any reason to believe it was	02:46
12	Q. Okay. Well, you know that it wasn't at	02:42	12	VAI?	02:46
13	the Little Falls facility; right?	02:42	13	A. No.	02:47
14	A. I didn't know whether there was some or	02:42	14	Q. Okay. I mean I could put the 2008 EIR	02:47
15	not. I didn't specifically look at that.	02:42	15	in front of you that explicitly says that.	02:47
16	Q. I see. Okay. So what you didn't know	02:42	16	A. Yeah.	02:47
17	is whether there was packaging in another facility	02:42	17	Q. Okay.	02:47
18	and also at the Little Falls facility.	02:42	18	A. Yeah.	02:47
19	A. That's correct.	02:42	19	Q. So VAI is a reasonable outcome for an	02:47
20	Q. Okay. Would you look at -- well, after	02:42	20	FDA inspection; correct?	02:47
21	this inspection, another a 483 was issued. Do you	02:42	21	A. It's reasonable in that they're not	02:47
22	remember that?	02:42	22	forcing you to do something specifically, that	02:47
23	A. Specifically, no.	02:42	23	it's up to you to do it, yes.	02:47
24	Q. All right. Well, look at page 44 of	02:43	24	Q. Everybody would love to have NAI for all	02:47
25	your report.	02:43	25	--	02:47

60 (Pages 234 to 237)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 238			Page 240		
1	A. Absolutely.	02:47	1	forth, of course you are free to.	02:49
2	Q. -- for all inspections; right?	02:47	2	THE WITNESS: I do because I want to make	02:49
3	A. Absolutely.	02:47	3	sure the redactions don't interrupt with the	02:49
4	Q. But VAI with three modest observations,	02:47	4	current version we're looking at.	02:50
5	that's a favorable outcome for an inspection,	02:47	5	MR. KERENSKY: Fair enough.	02:50
6	wouldn't you agree?	02:47	6	BY MR. ANDERTON:	02:50
7	A. I wouldn't necessarily agree that it's a	02:47	7	Q. What do you mean interrupt?	02:50
8	modest observation.	02:47	8	A. Well, I wrote my report based on this	02:50
9	Q. Well, after --	02:47	9	document that has redactions into it and this	02:50
10	A. It's better to have -- as you said, you	02:48	10	doesn't. So I want would make sure that there's	02:50
11	know, the real goal is no action indicated. And	02:48	11	no gaps. That's all it is.	02:50
12	the next step up is voluntary action indicated.	02:48	12	Q. Okay. Gaps? What do you mean gaps?	02:50
13	Q. If they weren't modest or not major at	02:48	13	A. Specifically, I don't know. I just want	02:50
14	least, there would have been an OAI outcome;	02:48	14	to make sure. This is the one I reviewed	02:50
15	right?	02:48	15	specifically, the second document. I'm just more	02:50
16	A. Potentially. It's one of those gray	02:48	16	comfortable doing that.	02:50
17	areas in the industry. If the agency sees you're	02:48	17	Q. Okay. Dr. Bliesner, under the heading	02:50
18	progressing and even though there are some	02:48	18	voluntary corrections on page 25 --	02:50
19	significant failures and you're implementing a	02:48	19	A. Yes.	02:50
20	corrective action, then they'll go okay, VAI.	02:48	20	Q. -- the FDA indicates that during this	02:50
21	Q. Okay. But a VAI is a reasonable	02:48	21	inspection, corrections to the previous FDA 483	02:50
22	outcome?	02:48	22	were reviewed with Ms. Ang. Do you see that?	02:50
23	A. It's reasonable.	02:48	23	A. I do, sir.	02:50
24	Q. Okay. A lot of companies never get	02:48	24	Q. So that would be the 483 that was issued	02:50
25	anything but VAI outcomes; right?	02:48	25	in August 2006 that resulted in a warning letter	02:50
Page 239			Page 241		
1	A. I don't know lots. I mean, you know,	02:48	1	in February of 2007; right?	02:50
2	that's a broad term.	02:48	2	A. Yes.	02:50
3	Q. Okay. Now continuing on this in EIR,	02:48	3	Q. And the observation -- the EIR then goes	02:50
4	Dr. Bliesner, turn to page 25 of 40.	02:48	4	on to list all of the observations that were in	02:51
5	Are you there?	02:49	5	that prior 483. Do you see that? Starting at	02:51
6	A. I'm double checking.	02:49	6	page 25 and going all the way through, oh, all the	02:51
7	Q. Dr. Bliesner, we've already established	02:49	7	way to page 39 of the EIR; right?	02:51
8	that it's the same document.	02:49	8	A. So the question is, these are the	02:51
9	A. I agree.	02:49	9	observations from the previous inspection that	02:51
10	Q. Okay. Then you don't need to be looking	02:49	10	happened? I'm sorry. What date? I'm confused.	02:51
11	at both documents.	02:49	11	The one in 2006?	02:51
12	A. I'm more comfortable if I do; okay.	02:49	12	Q. Correct.	02:52
13	What was the question please?	02:49	13	A. Okay.	02:52
14	Q. I didn't ask a question. I merely	02:49	14	Q. Right.	02:52
15	wanted you to turn to page 25. I asked -- the	02:49	15	A. It looks like it, yes. 483 to the EIR.	02:52
16	question? Are you at page 25?	02:49	16	Q. Okay.	02:52
17	A. I am.	02:49	17	A. Yes.	02:52
18	Q. Okay. Look at Exhibit 171. Okay,	02:49	18	Q. And so --	02:52
19	Dr. Bliesner, you've already conceded --	02:49	19	A. And there were -- how many did we have	02:52
20	A. Uh-huh.	02:49	20	here? They had 13 and they went back through all	02:52
21	Q. -- that is the same EIR. There's no	02:49	21	13, yes.	02:52
22	reason to keep referring back and forth between	02:49	22	Q. Okay.	02:52
23	the two documents; all right? Now --	02:49	23	A. Uh-huh.	02:52
24	MR. KERENSKY: And, Dr. Bliesner, if you	02:49	24	Q. So at this point during this 2007	02:52
25	feel more comfortable referring back and	02:49	25	inspection, as you might expect from -- as you	02:52

61 (Pages 238 to 241)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 242		Page 244	
1	indicated you might expect in the ordinary course,	1	A. Yes.
2	the FDA reviewed the corrective actions taken by	2	Q. So you made a point of noting the
3	Activis and assessed them or evaluated them;	3	observations that the FDA issued after that
4	correct?	4	inspection; right?
5	A. According to the EIR, yes.	5	A. That's correct.
6	Q. You place great weight on FDA documents,	6	Q. You didn't note the corrective actions.
7	don't you, Dr. Bliesner?	7	A. That was not my intent to do a search
8	A. I do.	8	and review the documentations to look for
9	Q. Okay. This EIR is no different than all	9	corrective actions.
10	the other FDA document you give significant weight	10	Q. A search. You didn't have to search.
11	to, is it?	11	You read it.
12	A. No.	12	A. Yes.
13	Q. Okay. It gets the same level of	13	Q. You knew they did the corrective action
14	credibility --	14	if you read the documents. You chose not to
15	A. I'm sorry. I don't know if I understand	15	include that positive fact in your report; right?
16	your consternation there.	16	A. I suppose so, yes.
17	Q. Don't worry about it.	17	Q. Okay. It seems awfully selective,
18	A. Okay, okay.	18	Dr. Bliesner, don't you think so?
19	Q. Dr. Bliesner, did you review this	19	A. No, not at all.
20	section of this EIR when you looked at it as you	20	Q. Okay.
21	compiled your report?	21	A. I was looking for patterns of lack of
22	A. Yes.	22	compliance which continued all the way up to the
23	Q. You did?	23	second consent decree.
24	A. I did.	24	Q. Except that in the eyes of the FDA, all
25	Q. So you must have known then in the eyes	25	prior GMP deficiencies had been corrected as of
Page 243		Page 245	
1	of the FDA, all of the GMP deficiencies that were	1	the time this inspection occurred, except for
2	part of the 2006 483 and the 2007 warning letter	2	those three new observations.
3	were remediated to the FDA's satisfaction; right?	3	A. Of the original observations, yes.
4	A. I can't say all definitively. They have	4	Q. So as of the time that inspection was
5	made progress and their observations were -- are	5	completed, in the eyes of the FDA, the GMP
6	here. I have to go back and look and say all is a	6	deficiencies that existed at Activis Totowa were
7	broad term. They addressed them, yes.	7	those three observations?
8	Q. And the document speaks for itself. It	8	A. At that point, yes.
9	will show --	9	Q. Okay. So when you say in a broad,
10	A. Okay.	10	sweeping fashion that they continued right up
11	Q. -- whether the FDA believed there was	11	through the second consent decree, that's not
12	any unresolved corrective actions; right?	12	accurate, is it?
13	A. If the document -- I haven't reviewed it	13	A. I disagree. You can correct actions and
14	in a while. If it says that, then it's true.	14	put them in place but still not change the
15	Q. So as you look -- as I look at your	15	fundamental systems. You can correct the
16	report on pages 15 and 16 --	16	procedures but you didn't necessarily change the
17	A. Uh-huh.	17	system, and that was shown when they got a second
18	Q. -- in chronological progression, you	18	consent decree after this.
19	refer to this EIR or to the inspection that is	19	Q. The FDA audited all of those systems;
20	reflected in this 2007 EIR, and you make a point	20	right?
21	to identify the three observations that the FDA	21	A. If this was done under the compliance
22	issued following that inspection. Do you see that	22	program guidance manual where they look at quality
23	beginning at the top of page -- I'm sorry, the	23	systems base, there was a turn in here. Let me
24	bottom of page 15 and continuing on to 16,	24	just check because the agency hasn't always looked
25	paragraph 37?	25	at it from a quality systems standpoint.

62 (Pages 242 to 245)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 246		Page 248	
1	Q. Well, Dr. Bliesner, you already 02:58	1	Looking at this cover document right now, I'm 03:00
2	acknowledged that the FDA conducted an inspection 02:58	2	not sure whether they implemented the new quality 03:00
3	of five of the six major systems. The only one 02:58	3	systems-based approach further. 03:00
4	not there is packaging and labeling; right? 02:58	4	Q. Do you have any reason to believe they 03:00
5	A. That's correct. 02:58	5	didn't? 03:00
6	Q. So the FDA issued its written opinion 02:58	6	A. Potentially, yes. 03:00
7	that the company had corrected all outstanding 02:58	7	Q. What's that? 03:00
8	previously identified GMP deficiencies except for 02:59	8	A. Because if I'm not mistaken -- and we 03:00
9	the three new ones that they identified as of the 02:59	9	can look it up -- the next inspection which 03:00
10	time they conducted this inspection; is that 02:59	10	resulted in the consent decree, they specifically 03:00
11	right? 02:59	11	say this inspection was conducted using the FDA 03:00
12	A. They corrected the actions that they had 02:59	12	compliance program guidance manual and the number. 03:00
13	made the observations on. 02:59	13	Q. Okay. So -- 03:00
14	Q. Okay. So -- 02:59	14	A. And I don't see that they did that 03:00
15	A. That doesn't mean it was a systems-based 02:59	15	here. That's why I'm bringing up the point. I'm 03:00
16	correction. It was a correction of those specific 02:59	16	not trying to be difficult. I just -- again, the 03:00
17	actions. 02:59	17	agency's made significant progress over the course 03:00
18	Q. Do you want go through each one, 02:59	18	since like 2002 when they adopted the quality 03:01
19	Dr. Bliesner? You're so insistent on qualifying 02:59	19	systems-based approach and they didn't necessarily 03:01
20	your responses -- again to keep doors open as 02:59	20	implement it in full force all the way out. 03:01
21	you've been coached to do -- that you can't 02:59	21	That's all it is. 03:01
22	concede the FDA -- the viability of this FDA 02:59	22	Q. So you're going to, as I said, that's a 03:01
23	document. You can't have it both ways. 02:59	23	long-winded way of saying you're going to 03:01
24	Do you understand that? 02:59	24	discredit this FDA document and give some limited 03:01
25	MR. KERENSKY: Objection, form. 02:59	25	weight to others. 03:01
Page 247		Page 249	
1	BY MR. ANDERTON: 02:59	1	A. I'm not discrediting it all; okay? As a 03:01
2	Q. If you want to give credit to FDA 02:59	2	matter of fact, all right, we're back on Exhibit 03:01
3	documents -- 02:59	3	171. I missed when we went first through. 03:01
4	A. Yes. 02:59	4	Q. And look at that -- 03:01
5	Q. -- as a substantial basis for your 02:59	5	A. Inspection. 03:01
6	opinion -- 02:59	6	Q. Inspectional guidance was afforded -- 03:01
7	A. Yes. 02:59	7	A. Through compliance program and guidance 03:01
8	Q. -- you must credit the documents that 02:59	8	manuals. 73506002. So with that being said, yes, 03:01
9	don't necessarily align with your opinion. You 02:59	9	they would use the newest guidance documents to 03:01
10	understand that; right? 02:59	10	look at it from a quality systems-based approach. 03:01
11	MR. KERENSKY: Objection form. Not a 02:59	11	Q. So does that change your earlier 03:01
12	true statement. 03:00	12	testimony or allow you to accept the fact that as 03:01
13	THE WITNESS: I would disagree with that. 03:00	13	of the date, this inspection was concluded in the 03:01
14	BY MR. ANDERTON: 03:00	14	eyes of the FDA? 03:01
15	Q. You can pick and choose? 03:00	15	A. Uh-huh. 03:01
16	A. I'm not picking and choosing. It's just 03:00	16	Q. Activis had corrected all prior GMP 03:01
17	that there's been a progression with the FDA's 03:00	17	deficiencies and the only GMP deficiencies the FDA 03:02
18	inspection procedures over the years. 03:00	18	identified were the three new ones that are set 03:02
19	Q. Right. 03:00	19	forth in that -- after this inspection. 03:02
20	A. Where they would go in and look at these 03:00	20	A. They corrected all of the findings that 03:02
21	major components; right? But they wouldn't 03:00	21	came up with the 483. I wouldn't -- I'm not 03:02
22	necessarily look at their internal document that 03:00	22	disputing that at all. 03:02
23	says how you do an inspection by a quality 03:00	23	Q. Okay. 03:02
24	systems-based approach. That didn't happen until 03:00	24	A. All right. 03:02
25	later on. 03:00	25	Q. And after -- 03:02

63 (Pages 246 to 249)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 250			Page 252		
1	A. And they were recidivistic though	03:02	1	something other than what you asked him.	03:03
2	because obviously they went back to their old	03:02	2	MR. ANDERTON: No, because --	03:03
3	ways. That's why they got a consent decree.	03:02	3	MR. KERENSKY: Your objection is	03:03
4	That's the real problem with companies ending up	03:02	4	unresponsive, not to stop him from talking and	03:03
5	in consent decree. They will get through warning	03:02	5	tell him he's just -- he's not answering.	03:03
6	letters, you know --	03:02	6	MR. ANDERTON: Mike, if you want to clean	03:03
7	Q. Dr. Bliesner, there's no question	03:02	7	this up with questions, you certainly may.	03:03
8	pending.	03:02	8	We're going to move on.	03:03
9	A. Oh, I'm sorry.	03:02	9	MR. KERENSKY: I'm sorry. We're going to	03:03
10	MR. KERENSKY: No, I'm sorry. He can say	03:02	10	stop the deposition until he finishes his	03:03
11	whatever in his question and you can't stop	03:02	11	answer.	03:03
12	him.	03:02	12	MR. ANDERTON: No we're not -- there is	03:03
13	MR. ANDERTON: No, he can't, Mike. There	03:02	13	no question pending, Mike.	03:03
14	was no --	03:02	14	MR. KERENSKY: There is.	03:03
15	MR. KERENSKY: Non-responsive, that's	03:02	15	MR. ANDERTON: No, there isn't. He	03:03
16	your remedy.	03:02	16	answered my question.	03:03
17	MR. ANDERTON: There was no question	03:02	17	MR. KERENSKY: Tell you what. Let's have	03:04
18	pending.	03:02	18	the court reporter go back and read it.	03:04
19	MR. KERENSKY: He was still answering the	03:02	19	MR. ANDERTON: Mike, if you --	03:04
20	last question.	03:02	20	MR. KERENSKY: Read the question and the	03:04
21	MR. ANDERTON: No, he wasn't.	03:02	21	answer, please. And the answer and	03:04
22	MR. KERENSKY: Do not interrupt the	03:02	22	Mr. Anderton's interruption.	03:04
23	witness.	03:02	23	MR. ANDERTON: If you keep obstructing	03:04
24	MR. ANDERTON: He just started talking	03:02	24	this deposition and instructing the witness	03:04
25	gratuitously.	03:02	25	what to say, we're going to call the court.	03:04
Page 251			Page 253		
1	MR. KERENSKY: That is not true.	03:02	1	MR. KERENSKY: I think it's a good time	03:04
2	MR. ANDERTON: It is true. There's no	03:02	2	to call the court.	03:04
3	question pending.	03:03	3	MR. ANDERTON: I mean he was done and had	03:04
4	MR. KERENSKY: Are you refusing to let	03:03	4	moved on, and I was about to ask another	03:04
5	the witness continue his answer?	03:03	5	question, and he just started talking.	03:04
6	MR. ANDERTON: There is no answer, Mike.	03:03	6	MR. KERENSKY: I accept your invitation	03:04
7	MR. KERENSKY: Are you refusing to let	03:03	7	to call the court so he can hear the last	03:04
8	the witness finish his answer?	03:03	8	question, the last answer, your interruption.	03:04
9	MR. ANDERTON: He finished his answer and	03:03	9	MR. ANDERTON: There is no interruption.	03:04
10	then just started talking again without a	03:03	10	I interrupted something that he was saying in	03:04
11	question being posed to him.	03:03	11	response to no question.	03:04
12	MR. KERENSKY: Are you refusing to let	03:03	12	MR. KERENSKY: That is not my take on it,	03:04
13	the witness finish his answer?	03:03	13	but your remedy if you think that, is to say	03:04
14	MR. ANDERTON: Mike, you can't instruct	03:03	14	unresponsive.	03:04
15	him to talk. There's no question pending.	03:03	15	MR. ANDERTON: Your remedy is to clear it	03:04
16	MR. KERENSKY: I'm not -- there is a	03:03	16	up if you think there's something here was	03:04
17	question pending.	03:03	17	answering in response to one of my questions.	03:04
18	MR. ANDERTON: No, there is not.	03:03	18	You have that right. Now we're moving on.	03:04
19	MR. KERENSKY: You interrupted him. Are	03:03	19	MR. KERENSKY: I do not think that. And	03:04
20	you refusing to let him finish his answer?	03:03	20	no, he's not going to ask answer any more	03:04
21	THE WITNESS: He's finished his answer.	03:03	21	questions until you let him finish his	03:05
22	I'm not refusing anything.	03:03	22	answer.	03:05
23	MR. KERENSKY: I'm sorry. The record is	03:03	23	MR. ANDERTON: What's the basis for you	03:05
24	real clear. You interrupted him and told him	03:03	24	instructing him not to answer?	03:05
25	to stop because you thought he was answering	03:03	25	MR. KERENSKY: Because you interrupted	03:05

64 (Pages 250 to 253)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 254			Page 256		
1	him.	03:05	1	MR. KERENSKY: And then you can object.	03:07
2	MR. ANDERTON: There was no question	03:05	2	MR. ANDERTON: And I object to you to	03:07
3	pending.	03:05	3	your speaking --	03:07
4	MR. KERENSKY: I'm sorry. There was.	03:05	4	MR. KERENSKY: There are three choices	03:07
5	MR. ANDERTON: There wasn't, Mike. Now,	03:05	5	you've got right now. Pick one.	03:07
6	I'm not going to argue with you anymore. This	03:05	6	MR. ANDERTON: I'm sorry. Are you --	03:07
7	is ridiculous.	03:05	7	THE WITNESS: Can I take a break?	03:08
8	MR. KERENSKY: Okay. Well, Dr. Bliesner,	03:05	8	MR. KERENSKY: Yeah, go ahead Dave.	03:08
9	start packing up.	03:05	9	MR. ANDERTON: Wait a minute. I'm sorry,	03:08
10	MR. ANDERTON: You cannot instruct him to	03:05	10	Mike. Do you get to decide now?	03:08
11	stop the deposition, Mike.	03:05	11	MR. KERENSKY: Yeah.	03:08
12	MR. KERENSKY: Sure I can.	03:05	12	MR. ANDERTON: This witness is stopping	03:08
13	MR. ANDERTON: No, you can't.	03:05	13	this deposition every 30 minutes. Why are we	03:08
14	MR. KERENSKY: I just did. Until he	03:05	14	doing that?	03:08
15	finishes that answer, we're not going to do	03:05	15	MR. KERENSKY: Because I don't know.	03:08
16	any more, or we can call the judge.	03:05	16	It's a very grueling deposition. You're one	03:08
17	MR. ANDERTON: Read the question back,	03:05	17	of the toughest guys I've been around in a	03:08
18	Phil.	03:05	18	long time. It's very difficult.	03:08
19	MR. KERENSKY: There you go. And the	03:05	19	MR. ANDERTON: Mike, stop. Why are we	03:08
20	answer and the interruption, please, Phil.	03:05	20	stopping every 30 minutes?	03:08
21	(Whereupon, the testimony was read	03:07	21	THE WITNESS: Because I got to go to the	03:08
22	back by the court reporter, as recorded above)	03:07	22	bathroom.	03:08
23	MR. ANDERTON: So what that shows, Mike,	03:07	23	MR. ANDERTON: Then go to the restroom.	03:08
24	is that in fact --	03:07	24	THE VIDEOGRAPHER: The time is 3:10 p.m.	03:08
25	MR. KERENSKY: I am not done listening,	03:07	25	We are going off the record.	03:08
Page 255			Page 257		
1	Michael.	03:07	1	(Short break)	03:17
2	MR. ANDERTON: Listen carefully, Mike,	03:07	2	THE VIDEOGRAPHER: The time is 3:19 p.m.	03:17
3	because what you'll see that in fact	03:07	3	We are back on the record. This is the	03:17
4	Dr. Bliesner interrupted my question.	03:07	4	beginning of tape seven.	03:17
5	MR. KERENSKY: That's an interesting	03:07	5	MR. KERENSKY: I would like the court	03:17
6	interpretation.	03:07	6	reporter to finish reading the witness's last	03:17
7	MR. ANDERTON: Read it back, Phil.	03:07	7	answer and I ask he be allowed to finish that	03:17
8	(Whereupon, the testimony was read	03:07	8	answer.	03:17
9	back by the court reporter, as recorded above)	03:07	9	MR. ANDERTON: Go head, Phil.	03:18
10	MR. KERENSKY: Your question obviously	03:07	10	(Whereupon, the testimony was read	03:18
11	interrupted his answer inadvertently that time	03:07	11	back by the court reporter, as recorded above)	03:18
12	and then the second time intentionally.	03:07	12	MR. KERENSKY: That's a good place to	03:18
13	MR. ANDERTON: Mike, not true. Read it	03:07	13	stop. Dr. Bliesner, do you need to add to	03:18
14	back.	03:07	14	that answer?	03:18
15	MR. KERENSKY: That's my take on it.	03:07	15	THE WITNESS: Read the last part of that	03:18
16	MR. ANDERTON: Read it back, Phil.	03:07	16	again, please. Just the -- not the whole	03:18
17	MR. KERENSKY: I'm telling you I'm not	03:07	17	thing, just the last sentence.	03:18
18	going to let you do this. I'm not going to	03:07	18	(Whereupon, the testimony was read	03:18
19	let you do it. Call the judge now. It's real	03:07	19	back by the court reporter, as recorded above)	03:18
20	simple. We can call the judge now, we can	03:07	20	And try to implement corrective actions.	03:18
21	stop the deposition, or you can stop, let him	03:07	21	And when they do so, they're not	03:18
22	say what he wants to say, and to finish this	03:07	22	systems-based, quality systems-based and they	03:18
23	question to talk about recidivism.	03:07	23	go right back to it because it's a culture	03:19
24	MR. ANDERTON: There was no question	03:07	24	that comes along with it. And it's not a true	03:19
25	about that.	03:07	25	corrective action that stands up to scrutiny.	03:19

65 (Pages 254 to 257)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

<p style="text-align: right;">Page 258</p> <p>1 MR. ANDERTON: Move to strike that entire 03:19</p> <p>2 speech as utterly non-responsive. Responsive 03:19</p> <p>3 to no pending question. 03:19</p> <p>4 BY MR. ANDERTON: 03:19</p> <p>5 Q. The -- you testified last time 03:19</p> <p>6 Dr. Bliesner that -- and I want to read it because 03:19</p> <p>7 I think it is interesting and because I'd like to 03:19</p> <p>8 be accurate. 03:20</p> <p>9 Mr. Moriarty asked you a question at page 117 03:20</p> <p>10 and carrying over on to page 118. You gave a 03:20</p> <p>11 response and during that response you said, and I 03:20</p> <p>12 quote: "This is the first time I went up to my 03:20</p> <p>13 medicine cabinet and I looked for anything that 03:20</p> <p>14 had an Activis label on it and flushed it down the 03:20</p> <p>15 toilet because it was that gross in terms of what 03:20</p> <p>16 I was seeing." 03:20</p> <p>17 Do you remember that testimony? 03:20</p> <p>18 A. I do. 03:20</p> <p>19 Q. What did you flush down the toilet? 03:20</p> <p>20 A. Products that had Activis's name on it. 03:21</p> <p>21 Q. Such as? 03:21</p> <p>22 A. I don't recall specifically. 03:21</p> <p>23 Q. Did you have products that had Activis's 03:21</p> <p>24 name on it? 03:21</p> <p>25 A. I did. 03:21</p>	<p style="text-align: right;">Page 260</p> <p>1 Q. You threw open the door and you flushed 03:21</p> <p>2 medicine down the toilet. 03:21</p> <p>3 A. I did. 03:21</p> <p>4 Q. Was that medicine manufactured by 03:21</p> <p>5 Activis Elizabeth or Activis Totowa? 03:21</p> <p>6 A. I wouldn't know. It didn't say on the 03:22</p> <p>7 bottle. 03:22</p> <p>8 Q. You didn't even check, did you? 03:22</p> <p>9 A. I don't believe that the bottle tells 03:22</p> <p>10 you where it's manufactured. 03:22</p> <p>11 Q. You didn't check, did you? 03:22</p> <p>12 A. I didn't have to. 03:22</p> <p>13 Q. Sure you did. What do you mean you 03:22</p> <p>14 didn't have to? 03:22</p> <p>15 A. Because of the failure in the quality 03:22</p> <p>16 systems that I had seen in reviewing the document, 03:22</p> <p>17 I didn't want to take any of the company's 03:22</p> <p>18 product. 03:22</p> <p>19 Q. Well, do you know anything about the 03:22</p> <p>20 distinction between Activis Totowa and Activis 03:22</p> <p>21 Elizabeth? 03:22</p> <p>22 A. From a business standpoint, not 03:22</p> <p>23 specifically. 03:22</p> <p>24 Q. Do you know who manufactured what 03:22</p> <p>25 products? 03:22</p>
<p style="text-align: right;">Page 259</p> <p>1 Q. How many? 03:21</p> <p>2 A. I don't recall. I think one bottle. 03:21</p> <p>3 Q. One bottle. Was it for you or for 03:21</p> <p>4 another family member? 03:21</p> <p>5 A. It was for me. 03:21</p> <p>6 Q. So you don't even know what you flushed 03:21</p> <p>7 down the toilet. 03:21</p> <p>8 A. I don't recall. It was a such a gross 03:21</p> <p>9 failure of compliance I didn't want to be putting 03:21</p> <p>10 it in my body. 03:21</p> <p>11 Q. Well, you had to go out and replace it; 03:21</p> <p>12 right? It was a prescription medication? 03:21</p> <p>13 A. Yes. 03:21</p> <p>14 Q. So what did you go replace? 03:21</p> <p>15 A. You'll find somebody else that 03:21</p> <p>16 manufactures. You ask the pharmacist to give you 03:21</p> <p>17 a different replacement. 03:21</p> <p>18 Q. What was it? What did you replace? 03:21</p> <p>19 A. I don't recall what I replaced 03:21</p> <p>20 Q. Well, it was sometime in the last 12 03:21</p> <p>21 months. You don't remember? 03:21</p> <p>22 A. No. 03:21</p> <p>23 Q. That seems like a pretty striking 03:21</p> <p>24 event. You ran up to your medicine cabinet. 03:21</p> <p>25 A. Yes, sir. 03:21</p>	<p style="text-align: right;">Page 261</p> <p>1 A. If I go back and review, I can piece 03:22</p> <p>2 together a list. 03:22</p> <p>3 Q. Well, you shouldn't -- 03:22</p> <p>4 A. I can't right off the top of my head. 03:22</p> <p>5 Q. You shouldn't have any information about 03:22</p> <p>6 Activis Elizabeth. They're not party to this 03:22</p> <p>7 lawsuit. Do you know that Activis Elizabeth and 03:22</p> <p>8 Activis Totowa work out of two totally different 03:22</p> <p>9 facilities? 03:22</p> <p>10 A. I know they are two different locations, 03:22</p> <p>11 yes. 03:22</p> <p>12 Q. And you know they have two totally 03:22</p> <p>13 different quality systems? 03:22</p> <p>14 A. No, I don't. 03:22</p> <p>15 Q. Different leadership? 03:22</p> <p>16 A. No, I don't. 03:22</p> <p>17 Q. Different personnel? 03:22</p> <p>18 A. No, I don't. 03:22</p> <p>19 Q. Didn't bother to try to find out, did 03:22</p> <p>20 you? 03:22</p> <p>21 A. I was told not to review them. 03:22</p> <p>22 Q. I'm talking about when you were in such 03:23</p> <p>23 a hurry to flush your medicine down the toilet, 03:23</p> <p>24 you didn't bother to try to find out whether that 03:23</p> <p>25 product came from Activis Totowa or from Activis 03:23</p>

66 (Pages 258 to 261)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 262			Page 264		
1	Elizabeth or from another Activis entity.	03:23	1	Q. Yes.	03:25
2	A. No, I didn't.	03:23	2	A. No.	03:25
3	Q. Is that a logical, reasoned reaction to	03:23	3	Q. Did you ever work for the FDA?	03:25
4	anything?	03:23	4	A. No.	03:25
5	A. Yes.	03:23	5	Q. Did you ever spend any time inside	03:25
6	Q. You said last time that -- you made	03:23	6	either one of the various branches? Well not	03:25
7	reference to your belief or you indicated -- I	03:23	7	either one. Any of the various branches of the	03:26
8	shouldn't say may reference to -- you indicated	03:23	8	FDA?	03:26
9	your belief that the FDA puts things on its	03:23	9	A. No.	03:26
10	website that are pure politics.	03:23	10	Q. So you believe that when one branch	03:26
11	Do you remember that testimony?	03:23	11	issues something that isn't necessarily consistent	03:26
12	A. I did not make that blanket statement	03:23	12	with something issued by another branch, it's	03:26
13	that I recall.	03:24	13	strictly politics?	03:26
14	Q. Well, let me ask you this.	03:24	14	A. Not strictly. There are components to	03:26
15	A. Okay.	03:24	15	it that do arise. For instance, drug shortage	03:26
16	Q. When you conducted an analysis that you	03:24	16	often has serious discussions with compliance	03:26
17	did to issue your opinion in this case --	03:24	17	group because they have different missions	03:26
18	A. Yes.	03:24	18	Q. Have you ever been party to any of those	03:26
19	Q. -- did you do a political analysis or	03:24	19	discussions?	03:26
20	some other type of analysis?	03:24	20	A. Directly, no.	03:26
21	A. I reviewed the documentation as I would	03:24	21	Q. So you have no idea what is said in	03:26
22	if I was a client in the facility looking for data	03:24	22	those discussions between -- I'm sorry drug	03:26
23	to support whatever conclusions come up.	03:24	23	shortage and compliance; right?	03:26
24	Q. Is that a political analysis?	03:24	24	A. Meaning the folks that are in charge of	03:26
25	A. No.	03:24	25	making sure they're supplied to market and the	03:26
Page 263			Page 265		
1	Q. Did politics enter into your analysis at	03:24	1	compliance people.	03:26
2	all?	03:24	2	Q. You have no idea what's ever been said	03:26
3	A. No.	03:24	3	in any of those conversations; right?	03:26
4	Q. Are you an expert in politics?	03:24	4	A. That's not true.	03:26
5	A. No.	03:24	5	Q. Have you ever been --	03:26
6	Q. Do you have anything to support your	03:24	6	A. I've not sat in meetings. I have	03:26
7	testimony that things the FDA puts on its website	03:24	7	clients convey it.	03:26
8	result from politics?	03:24	8	Q. Clients who sat in the meetings?	03:26
9	A. In my experience, there are sometimes	03:25	9	A. Yes.	03:27
10	competing opinions against different branches	03:25	10	Q. So you're getting it at least third	03:27
11	within FDA which appear to be -- appear to be	03:25	11	hand?	03:27
12	politically motivated.	03:25	12	A. Second-hand.	03:27
13	Q. Appear to be politically motivated?	03:25	13	Q. Second-hand?	03:27
14	A. Yes.	03:25	14	A. Yes.	03:27
15	Q. Bliesner on politics? Is that the	03:25	15	Q. Ever do anything to verify that?	03:27
16	source for that, Bliesner on politics?	03:25	16	A. Specifically, no.	03:27
17	A. No, it's not Bliesner on politics.	03:25	17	Q. I want to talk about --	03:27
18	Q. What observation -- what supports that	03:25	18	A. Can you adjust the air-conditioning in	03:27
19	observation?	03:25	19	here? I'm starting to get to the same point.	03:27
20	A. My experience.	03:25	20	MS. DREWES: I will. But I tried earlier	03:27
21	Q. Do you have any political experience?	03:25	21	and she turned it down as much as she could.	03:27
22	A. Political?	03:25	22	Apparently it's an issue especially later in	03:27
23	Q. Yes.	03:25	23	the day when the sun comes around.	03:27
24	A. Like in formal office or running for	03:25	24	MR. ANDERTON: Comes around this side of	03:27
25	anything like that?	03:25	25	the building.	03:27

67 (Pages 262 to 265)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 266			Page 268		
1	MR. KERENSKY: It's getting hot in here,	03:28	1	A. Engagements, you mean consulting	03:30
2	too. It must be coming right over the phone.	03:28	2	projects?	03:30
3	MR. ANDERTON: Yeah.	03:28	3	Q. Uh-huh.	03:30
4	BY MR. ANDERTON:	03:28	4	A. One for sure. It's still ongoing. And	03:30
5	Q. You produced today invoices that you	03:28	5	I may have had one other just briefly.	03:30
6	have submitted to the Plaintiffs' counsel for	03:28	6	Q. Any of them as big as this one?	03:30
7	payment; right?	03:28	7	A. And when you say "big," what do you mean	03:30
8	A. Yes.	03:28	8	by big?	03:30
9	Q. You said there's least one that's	03:28	9	Q. Well \$140,000, that's a reasonable	03:30
10	outstanding; right?	03:28	10	amount of revenue wouldn't you say?	03:30
11	A. Yes.	03:28	11	A. It is.	03:30
12	Q. I don't -- there is no detail on those	03:28	12	Q. I mean even at 550 an hour, that's 700	03:30
13	invoices. Do you have detailed time records that	03:28	13	hours; right? No, that's wrong.	03:30
14	show what you did and how many hours you spent	03:28	14	A. I can tell you this. I've been fully	03:31
15	besides a general summary as is set forth in these	03:28	15	engaged with a client since June.	03:31
16	invoices?	03:28	16	Q. In addition to this engagement?	03:31
17	A. I just have a spreadsheet where I did	03:28	17	A. Yes. This is on the side.	03:31
18	the work, I put the hour in and then I send that	03:28	18	Q. Oh, this is on the side?	03:31
19	to the bookkeeper.	03:28	19	A. Prior to -- it started prior to and then	03:31
20	Q. Okay. So you do have records?	03:28	20	this -- this has been done on weekends.	03:31
21	A. Uh-huh.	03:28	21	Q. Okay.	03:31
22	Q. Do you provide any description of what	03:28	22	A. I do anything about 60 to 90 hours a	03:31
23	you did during the --	03:28	23	week at that current client site. I have been	03:31
24	A. On those records?	03:28	24	since June.	03:31
25	Q. Yes.	03:28	25	Q. Okay. Will you pick up Exhibit 109?	03:31
Page 267			Page 269		
1	A. I don't believe so. There may be a word	03:28	1	A. Sure, if I can find it. Which one is	03:31
2	or two.	03:28	2	that, sir?	03:31
3	Q. Services rendered. Is that the --	03:28	3	Q. It's one of the sets of notes that you	03:31
4	A. I'd have to look at -- I'm fairly	03:28	4	produced that we took last time.	03:32
5	certain that I provided those sheets.	03:29	5	A. Yes, got it.	03:32
6	Q. On?	03:29	6	Q. I'm looking at the first page of 109.	03:32
7	A. The hard drive, I think.	03:29	7	Are you with me?	03:32
8	Q. Oh, in the hard drive?	03:29	8	A. I am.	03:32
9	A. I think so.	03:29	9	Q. Roman numeral I -- on 109, the first	03:32
10	Q. Okay.	03:29	10	page is as I read the heading, "Collective Proof	03:32
11	A. If not, I can get them for you.	03:29	11	of Adulterated Digitek Making it to Market."	03:32
12	Q. Do you know how much money you have	03:29	12	A. Yes.	03:32
13	billed and been paid from this engagement?	03:29	13	Q. The first item Roman numeral I is	03:32
14	A. To this point?	03:29	14	Adverse Event Reports; right?	03:32
15	Q. Yes.	03:29	15	A. Yes.	03:32
16	A. No.	03:29	16	Q. You are not a pharmacovigilance expert,	03:32
17	Q. Is there only one invoice that's	03:29	17	are you?	03:32
18	outstanding beyond this one?	03:29	18	A. I am not.	03:32
19	A. I'm fairly certain yes, there is.	03:29	19	Q. You don't know -- you're not able to	03:32
20	Q. Rough estimate puts it somewhere north	03:29	20	give any expert opinion about the reliability of	03:32
21	of \$140,000. Does that sound right?	03:29	21	the facts and circumstances in adverse event	03:32
22	A. If you add it up and that's what the	03:30	22	reports, are you?	03:33
23	number is, then it is. I really don't know.	03:30	23	A. No, this was based on observation that	03:33
24	Q. How many other engagements did you have	03:30	24	was in one of the EIRs. I'd have to look.	03:33
25	in 2010?	03:30	25	Q. Okay. What you mean by that?	03:33

68 (Pages 266 to 269)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 270			Page 272		
1	A. There was a -- in reviewing, if I'm not	03:33	1	A. Yes.	03:35
2	mistaken an EIR or 483, that this is one of the	03:33	2	Q. Which you've said you're not qualified	03:35
3	items the agency found specifically.	03:33	3	to evaluate.	03:35
4	There was a death within a certain period of	03:33	4	A. No, that's correct.	03:35
5	time or whatever, so...	03:33	5	Q. Okay.	03:35
6	Q. That was the report?	03:33	6	A. But the potential was there, which	03:35
7	A. Yes.	03:33	7	from -- would you like me to continue or stop? I	03:35
8	Q. That wasn't a finding of the EIR.	03:33	8	don't want to...	03:35
9	A. It was a report.	03:33	9	Q. You were answering.	03:35
10	Q. Yeah.	03:33	10	A. Okay. From a, you know, compliance	03:35
11	A. That there was a death from an adverse	03:33	11	standpoint, you look at that and you say to	03:35
12	event and it was not reported to the FDA.	03:33	12	yourself, jeez, if there was an adverse event, a	03:35
13	Q. So agency, to be clear --	03:33	13	person potentially passed away in two and a half	03:35
14	A. Uh-huh.	03:33	14	hours, you sit back and go okay, from a product	03:35
15	Q. -- the agency, the FDA didn't find that	03:33	15	standpoint, me working for this company again,	03:35
16	there was a death within several hours of taking	03:33	16	from a product standpoint, jeez, could that have	03:35
17	the product.	03:33	17	been product-related?	03:35
18	A. They found there was an adverse event	03:33	18	So you go look and you see it's immediate	03:35
19	that had not been reported to them that stated	03:33	19	dosage form, and you try to pull up the PK lead	03:35
20	that there was a death within a certain short	03:33	20	out of an ANDA. And if the PK says it's like six	03:35
21	period of time, yeah.	03:33	21	hours or whatever, you don't worry about it. You	03:35
22	Q. And, again, you're not qualified to	03:33	22	move on. It's not related to that. That's how	03:35
23	assess the reliability of the facts and	03:33	23	the logic went on that.	03:35
24	circumstances that are set forth in or were set	03:34	24	Q. Okay. And so is that proof that	03:35
25	forth in that adverse event, are you?	03:34	25	adulterated Digitek made it to market?	03:35
Page 271			Page 273		
1	A. No, but it triggered my eye because it	03:34	1	A. No, it's not proof.	03:35
2	was a short period of time for an immediate dose	03:34	2	Q. Okay. You characterize it as such in	03:35
3	of product, and it was like maybe there's	03:34	3	this document. That's just why I'm --	03:36
4	something. That was actually the first thing that	03:34	4	A. My notes --	03:36
5	got me started on this -- this review.	03:34	5	Q. Okay.	03:36
6	Q. Well, Dr. Bliesner, I'm a little bit	03:34	6	A. Proof is --	03:36
7	confused.	03:34	7	Q. So it's not proof?	03:36
8	A. Uh-huh.	03:34	8	A. No, it's not. It's a piece of data that	03:36
9	Q. You say -- when you make that statement	03:34	9	was the start of a potential pattern that was the	03:36
10	--	03:34	10	first thing -- quite honestly that was first thing	03:36
11	A. Uh-huh.	03:34	11	that caught my eye so I just started digging.	03:36
12	Q. -- you're presuming the accuracy or --	03:34	12	Q. I'm merely asking about your	03:36
13	I'm sorry. You're presuming the cause and effect	03:34	13	characterization in your document.	03:36
14	relationship between taking a product and the	03:34	14	A. Yes.	03:36
15	event set forth in the adverse event report,	03:34	15	Q. So it's not proof.	03:36
16	aren't you?	03:34	16	A. No.	03:36
17	A. Say that again specifically.	03:34	17	Q. And look at Roman numeral VI.	03:36
18	MR. ANDERTON: Phil, would you please	03:35	18	A. Okay.	03:36
19	read that back?	03:35	19	Q. Company internal documents and	03:36
20	(Whereupon, the testimony was read	03:35	20	investigations.	03:36
21	back by the court reporter, as recorded above)	03:35	21	A. Uh-huh.	03:36
22	THE WITNESS: There is a potential cause	03:35	22	Q. You see your reference to purchase	03:36
23	and effect there.	03:35	23	presses.	03:36
24	BY MR. ANDERTON:	03:35	24	A. Yes.	03:36
25	Q. Potential?	03:35	25	Q. How is that proof that adulterated	03:36

69 (Pages 270 to 273)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 274			Page 276		
1	Digitek made it to market?	03:36	1	Q. Well, let's call it an upgrade.	03:38
2	A. There were a couple of circumstances as	03:36	2	A. Uh-huh.	03:38
3	I recall where they had reasonable suspect that	03:36	3	Q. Doesn't mean you had problems before;	03:38
4	they had problems with tablet presses. So they	03:37	4	right?	03:38
5	committed -- if I'm not mistaken without taking	03:37	5	A. But they committed to the FDA and they	03:38
6	more time and going back and looking at the	03:37	6	didn't purchase them, as I recall.	03:38
7	document -- they would purchase new presses with	03:37	7	Q. You just changed the subject,	03:38
8	weight controls or whatever and they never did.	03:37	8	Dr. Bliesner.	03:38
9	And that happened over the course of a -- if I'm	03:37	9	A. I did?	03:38
10	not mistaken, going back to look at the book, a	03:37	10	Q. Yeah?	03:38
11	year or two.	03:37	11	A. I'm sorry.	03:38
12	Q. Okay. So you work with companies all	03:37	12	Q. I asked you if the mere act of upgrading	03:38
13	the time on GMP compliance; right?	03:37	13	presses means that they had problems.	03:38
14	A. That's correct.	03:37	14	A. Not specifically, no.	03:39
15	Q. And one of the things I'm sure you tell	03:37	15	Q. And so purchasing presses doesn't	03:39
16	them is that they ought to be constantly	03:37	16	constitute proof that there is adulterated Digitek	03:39
17	evaluating and reevaluating their quality systems;	03:37	17	in the market, does it?	03:39
18	right?	03:37	18	A. Not necessarily, no.	03:39
19	A. Absolutely. CGMP current today, not	03:37	19	Q. But you characterize it on that	03:39
20	yesterday.	03:37	20	document.	03:39
21	Q. Exactly. And so it's an evolutionary	03:37	21	A. It's my notes, uh-huh.	03:39
22	process.	03:37	22	Q. You understand, Dr. Bliesner?	03:39
23	A. Absolutely.	03:37	23	A. I do sir.	03:39
24	Q. Never stops evolving.	03:37	24	Q. That we get these documents.	03:39
25	A. No, it doesn't.	03:37	25	A. Uh-huh.	03:39
Page 275			Page 277		
1	Q. So upgrading presses or purchasing new	03:37	1	Q. And we get your report?	03:39
2	presses --	03:37	2	A. Uh-huh.	03:39
3	A. Uh-huh.	03:37	3	Q. And we are -- we have to try to figure	03:39
4	Q. -- doesn't say anything about whether	03:37	4	out --	03:39
5	adulterated product was produced or made it to	03:38	5	A. Uh-huh.	03:39
6	market, does it?	03:38	6	Q. -- how you reached the conclusions that	03:39
7	A. It doesn't say anything about whether	03:38	7	you reached.	03:39
8	adulterated products have made it to the market.	03:38	8	A. Correct.	03:39
9	Q. That's right.	03:38	9	Q. That's what we're doing today.	03:39
10	A. I wouldn't agree with that statement.	03:38	10	A. I understand.	03:39
11	It -- it shows they had problems.	03:38	11	Q. So I understand that this is your notes.	03:39
12	Q. It does?	03:38	12	A. Uh-huh.	03:39
13	A. It shows they had problems with the	03:38	13	Q. You're the one who characterized this as	03:39
14	presses because they said they had problems with	03:38	14	proof --	03:39
15	the presses.	03:38	15	A. Uh-huh.	03:39
16	Q. They didn't say they had problems. They	03:38	16	Q. -- that adulterated Digitek was in the	03:39
17	said they wanted to purchase new presses	03:38	17	market.	03:39
18	A. With weight control, if I remember	03:38	18	A. Uh-huh.	03:39
19	correctly.	03:38	19	Q. I'm just inquiring about some of these	03:39
20	Q. Okay. So that doesn't mean they're	03:38	20	things.	03:39
21	having problems; it means they're looking at a	03:38	21	A. Understood.	03:39
22	different technology.	03:38	22	Q. Excuse me?	03:40
23	A. Uh-huh.	03:38	23	A. Uh-huh.	03:40
24	Q. Right?	03:38	24	Q. Dr. Bliesner, would you now find Exhibit	03:40
25	A. Yes, an upgrade if you will.	03:38	25	107. It's another set of notes that we collected	03:40

70 (Pages 274 to 277)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 278			Page 280		
1	from you last time.	03:40	1	Do you see that?	03:42
2	A. May I see the top of?	03:40	2	A. I do.	03:42
3	Q. You may. It the thicker one. It's the	03:40	3	Q. 97.1 is well within specification for	03:42
4	Mylan deposition exhibits.	03:40	4	Digitex as approved by the FDA in the ANDA, isn't	03:42
5	A. I have it here.	03:40	5	it?	03:42
6	Q. Okay. You see on the first page there	03:40	6	A. I don't know. I'd have to go back and	03:42
7	it says probably equals more likely than not?	03:40	7	look at it.	03:42
8	A. Uh-huh.	03:40	8	Q. Well, didn't you -- I mean if you made a	03:42
9	Q. When did you write that?	03:40	9	note that something was out of spec.	03:42
10	A. I don't recall specifically, but I'm --	03:40	10	A. Somebody made a statement somewhere in	03:42
11	my suspect is it was the preparation meeting	03:40	11	this document whatever M09 was apparently. I'm	03:42
12	before the first deposition.	03:40	12	not going back and looking at it.	03:42
13	Q. Okay. And --	03:40	13	Q. I understand.	03:42
14	A. Because I was still struggling with that	03:40	14	A. That somebody made a statement you	03:42
15	whole concept of possible and probable.	03:40	15	realize that what this is, is not a detailed	03:42
16	Q. Well, you understand what probably	03:41	16	reading of these documents because the search	03:42
17	meant; right?	03:41	17	capabilities of that Crivella West I think is the	03:42
18	A. If I'm not mistaken I was told that's	03:41	18	name of it, is abysmal, so you can't find	03:43
19	what it was. It was a definition. These were	03:41	19	anything. So I just basically went in and said,	03:43
20	my -- my documents that I had laid out as an	03:41	20	pulled up 01, skimmed it. If I saw something, you	03:43
21	indices in the discussion, and it was the first	03:41	21	know -- well, I tried to do a thumbnail summary on	03:43
22	thing I wrote on, so...	03:41	22	there so later on if I needed to go pull it up, I	03:43
23	Q. Okay. So you wrote in your discussions	03:41	23	would. So --	03:43
24	with Plaintiffs' counsel, that probably equals	03:41	24	Q. Okay.	03:43
25	more likely than not; right?	03:41	25	A. Obviously -- or maybe not obviously --	03:43
Page 279			Page 281		
1	A. I'm fairly confident that's what they	03:41	1	it looks as if I probably printed that one and	03:43
2	mentioned to me as the definition.	03:41	2	it's somewhere in the stack.	03:43
3	Q. Okay. And the very next day --	03:41	3	Q. And you acknowledge of course that --	03:43
4	A. Uh-huh.	03:41	4	that the fact that it might -- that UDL might have	03:43
5	Q. -- you testified that you did not know	03:41	5	or Mylan might have a tighter specification says	03:43
6	the difference between possibility and	03:41	6	nothing about whether the product is actually out	03:43
7	probability?	03:41	7	of specification; correct?	03:43
8	A. Obviously I was still confused with	03:41	8	A. That's correct.	03:43
9	that.	03:41	9	Q. At the end of the day, the operative	03:43
10	Q. And in the same meeting where you wrote	03:41	10	number with respect to whether something is in or	03:43
11	probably equals more likely than not -- well,	03:41	11	out of specification is the number the number for	03:43
12	strike that.	03:41	12	any particular attribute set forth in the ANDA; is	03:43
13	A. I --	03:41	13	that right?	03:44
14	Q. Strike that.	03:41	14	A. The approved application; that's	03:44
15	A. Okay, okay.	03:41	15	correct.	03:44
16	Q. Look at the second page of Exhibit 107,	03:41	16	Q. Okay. So if you make a product and it's	03:44
17	please.	03:41	17	distributed by somebody else and they, the	03:44
18	A. Sure.	03:41	18	distributor prefers tighter specifications, that	03:44
19	Q. You made a note about Exhibit M09?	03:42	19	doesn't have any bearing on whether the product	03:44
20	A. Yes.	03:42	20	you make is actually out of specification, does	03:44
21	Q. You see that?	03:42	21	it?	03:44
22	A. Yes.	03:42	22	A. Tighter specs are always around.	03:44
23	Q. And you indicated outside of spec 98 to	03:42	23	Q. Okay.	03:44
24	103 percent. And then you parenthetically	03:42	24	A. It's an additional level of control.	03:44
25	indicated 97.1 percent.	03:42	25	Q. And if they had tighter specs and the	03:44

71 (Pages 278 to 281)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 282			Page 284		
1	product doesn't meet them but still falls within	03:44	1	A. What did you say?	03:47
2	the ANDA specifications, that product is within	03:44	2	Q. UDL to file from Lee Roedke, 16	03:47
3	specification; right?	03:44	3	September, abbreviated, 2006?	03:47
4	A. For the manufacturing service.	03:44	4	A. Uh-huh.	03:47
5	Q. Yes.	03:44	5	Q. Activis warning letter, Little Falls,	03:47
6	A. In this particular case. UDL probably	03:44	6	New Jersey. Did I read that correctly so far?	03:47
7	would have rejected it because that's their spec.	03:44	7	A. Yes.	03:47
8	Q. Fair enough, but with respect to that --	03:44	8	Q. It goes on to say not addressing FDA ADE	03:47
9	A. The original ap., yes.	03:44	9	concerns. Did I read that correctly?	03:47
10	Q. And with respect to whether it is out of	03:44	10	A. Yes.	03:47
11	spec, out of specification in the eyes of the FDA,	03:44	11	Q. And ADE concerns in that context is an	03:47
12	it is not out of specification; correct?	03:44	12	acronym for adverse drug events; correct?	03:48
13	A. I would say that's a fair statement,	03:44	13	A. Without specifically pulling it up, I	03:48
14	yes.	03:44	14	would say yes, that's true.	03:48
15	Q. Okay. Can you look at the page that	03:44	15	Q. Okay. Do you use ADE for any other	03:48
16	refers to Exhibit M44, please?	03:45	16	purpose in the context of performing your GMP	03:48
17	A. Sure, yes.	03:45	17	compliance consulting services?	03:48
18	Q. Did you -- do you recall enough about	03:45	18	A. No. But like you said, I'm not an	03:48
19	M44 from looking at this document to know whether	03:45	19	adverse drug event person.	03:48
20	you read it or not?	03:46	20	Q. This is your terminology.	03:48
21	A. I don't.	03:46	21	A. This is a summary.	03:48
22	Q. Okay. Your thumbnail sketch as you	03:46	22	Q. I understand.	03:48
23	described it indicates this is an e-mail from Sue	03:46	23	A. And, again, unless we pull it up, that	03:48
24	Powers to Chuck Kuhn, regarding the recall costs	03:46	24	may be what they refer to it as in the e-mail.	03:48
25	for UDL.	03:46	25	Chances are that's what it is.	03:48
Page 283			Page 285		
1	Do you see that?	03:46	1	Q. But you made the note.	03:48
2	A. I do.	03:46	2	A. Yes.	03:48
3	Q. You wrote that; right?	03:46	3	Q. Do you mean to use the term ADE to stand	03:48
4	A. Yes.	03:46	4	for adverse drug event?	03:48
5	Q. All right. So that's some brief	03:46	5	A. More than likely, yes.	03:48
6	characterization of what you saw when you read	03:46	6	Q. Okay.	03:48
7	that document?	03:46	7	A. Uh-huh.	03:48
8	A. I scanned it. I didn't read it, I	03:46	8	Q. I'm handing you, Dr. Bliesner, a	03:48
9	scanned it.	03:46	9	document that has been marked as Defendant's	03:48
10	Q. Do the costs of a recall have anything	03:46	10	Exhibit 87.	03:48
11	to do with whether there's adulterated or out of	03:46	11	A. Okay.	03:48
12	specification product in the market?	03:46	12	Q. Take a moment please and review that	03:48
13	A. I don't believe so.	03:46	13	document very briefly.	03:48
14	Q. Look at the page of Exhibit 107 that	03:46	14	A. Uh-huh.	03:48
15	refers to M56, please.	03:47	15	Q. Let me know when you have reviewed it.	03:48
16	A. 56?	03:47	16	A. Sure. Okay.	03:49
17	Q. Yes, please.	03:47	17	Q. Have you seen that document before?	03:49
18	A. Uh-huh.	03:47	18	A. I'm not sure.	03:49
19	Q. Do you see your handwritten note about	03:47	19	Q. All right. Well you see that -- that it	03:49
20	that?	03:47	20	is referencing a warning letter --	03:49
21	A. I do.	03:47	21	A. Uh-huh.	03:49
22	Q. And it says that UDL to file from Lee	03:47	22	Q. -- issued to Activis in August of 2006.	03:49
23	Roedke, 16 September, 2006, Activis warning	03:47	23	A. Uh-huh.	03:49
24	letter, Little Falls, New Jersey. Did I read that	03:47	24	Q. That relates to adverse drug	03:49
25	correctly so far?	03:47	25	experiences. Do you see that?	03:50

72 (Pages 282 to 285)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

<p style="text-align: right;">Page 286</p> <p>1 A. I do. 03:50</p> <p>2 Q. And this is the warning letter that you 03:50</p> <p>3 referred to earlier when you were talking about 03:50</p> <p>4 the reports and the ADE, and we talked for a 03:50</p> <p>5 moment about the connection, whether there's 03:50</p> <p>6 reliability in ADE reporting, and all that. It's 03:50</p> <p>7 the same point. 03:50</p> <p>8 A. I'll take your word. 03:50</p> <p>9 Q. So in this letter, the FDA accepts the 03:50</p> <p>10 corrective actions Activis has proposed and 03:50</p> <p>11 implemented with respect to that warning letter; 03:50</p> <p>12 right? 03:50</p> <p>13 A. Correct. 03:50</p> <p>14 Q. Okay. So when you wrote in response to 03:50</p> <p>15 or in connection with Exhibit M56 that Activis 03:50</p> <p>16 wasn't addressing the ADE concerns, is that 03:50</p> <p>17 accurate? 03:50</p> <p>18 A. It's what's in the e-mail more than 03:50</p> <p>19 likely -- or memo, whatever it is. 03:50</p> <p>20 Q. Okay. 03:50</p> <p>21 A. It's somebody, whoever that individual 03:50</p> <p>22 was. 03:50</p> <p>23 Q. Lee Roedke. 03:50</p> <p>24 A. Apparently that's who it was. Again 03:50</p> <p>25 this is a snapshot summary, glancing it at this. 03:51</p>	<p style="text-align: right;">Page 288</p> <p>1 uniformity test. 03:52</p> <p>2 Q. So by that you mean that you take a 03:52</p> <p>3 sample of the blend, you conduct a chemical test 03:52</p> <p>4 on it to determine the assay of that sample, and 03:53</p> <p>5 then you apply the specifications to determine 03:53</p> <p>6 whether that sample -- whether the assay value for 03:53</p> <p>7 that sample is within those specifications; 03:53</p> <p>8 correct? 03:53</p> <p>9 A. That's a fair assessment. 03:53</p> <p>10 Q. And so when you sample blends for 03:53</p> <p>11 testing to determine whether it is uniformly 03:53</p> <p>12 distributed -- excuse me -- most manufacturers 03:53</p> <p>13 take samples of blend in duplicate or triplicate; 03:53</p> <p>14 correct? 03:53</p> <p>15 A. Most manufacturers? I don't know if I 03:53</p> <p>16 can speak to most manufacturers, but there's more 03:53</p> <p>17 than one. 03:53</p> <p>18 Q. Okay. So it's not uncommon for a 03:53</p> <p>19 pharmaceutical manufacturer to take blend samples 03:53</p> <p>20 in duplicate or triplicate; right? 03:53</p> <p>21 A. I would say that's fair. 03:53</p> <p>22 Q. And that is an acceptable practice so 03:53</p> <p>23 long as you, the manufacturer, have an 03:54</p> <p>24 appropriately drafted SOP? 03:54</p> <p>25 A. Manufacturer, during process validation 03:54</p>
<p style="text-align: right;">Page 287</p> <p>1 Whether it's an e-mail, memo or whatever. 03:51</p> <p>2 Q. Okay. 03:51</p> <p>3 A. That's their concern I'm assuming, not 03:51</p> <p>4 going back and pulling it out. 03:51</p> <p>5 Q. Okay. Well -- 03:51</p> <p>6 A. Knee deep in paper. 03:51</p> <p>7 Q. Yeah. Unfortunately that's a necessary 03:51</p> <p>8 part of this process, Dr. Bliesner. All right. 03:51</p> <p>9 Find 108, please. 03:51</p> <p>10 A. Which one are we on, sir? 03:51</p> <p>11 Q. Exhibit 108. 03:51</p> <p>12 A. Exhibit 108. Yes, sir. 03:51</p> <p>13 Q. What do you mean when you use the term 03:52</p> <p>14 "blend uniformity failure." To you, what does 03:52</p> <p>15 that mean? 03:52</p> <p>16 A. Blend uniformity failure? 03:52</p> <p>17 Q. Yeah. 03:52</p> <p>18 A. It means that blend gets sampled and 03:52</p> <p>19 tested wouldn't necessarily, does not have the, 03:52</p> <p>20 you know, assay value that it was supposed to 03:52</p> <p>21 have. 03:52</p> <p>22 Q. At what point of the sampling and 03:52</p> <p>23 testing process does something become a blend 03:52</p> <p>24 uniformity failure? 03:52</p> <p>25 A. Well, there's a spec for blend 03:52</p>	<p style="text-align: right;">Page 289</p> <p>1 will come up with a sampling plan, and a sampling 03:54</p> <p>2 approach. Manufacturing does the sampling and 03:54</p> <p>3 delivers the sample for you. 03:54</p> <p>4 Q. So it is acceptable to draft a sampling 03:54</p> <p>5 plan with respect to blend sampling that calls for 03:54</p> <p>6 blend samples to be taken in duplicate or 03:54</p> <p>7 triplicate; right? 03:54</p> <p>8 A. At least, yes. 03:54</p> <p>9 Q. And it is acceptable to draft a testing 03:54</p> <p>10 plan. 03:54</p> <p>11 A. Yes. 03:54</p> <p>12 Q. For blend samples that allows for 03:54</p> <p>13 testing the second or third sample from a given 03:54</p> <p>14 location under appropriate circumstances; right? 03:54</p> <p>15 A. Content uniformity, yeah, under 03:54</p> <p>16 appropriate circumstances. 03:54</p> <p>17 Q. Well, so -- so it is -- you've seen and 03:55</p> <p>18 it is okay to have a sampling plan that says you 03:55</p> <p>19 take blend samples in triplicate, for example. 03:55</p> <p>20 A. Uh-huh. 03:55</p> <p>21 Q. You test the first sample from each 03:55</p> <p>22 location and in appropriate circumstances if -- if 03:55</p> <p>23 one of those samples is not tested within 03:55</p> <p>24 specification, you may test the second sample from 03:55</p> <p>25 that location. 03:55</p>

73 (Pages 286 to 289)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 290	Page 292
<p>1 A. Same location. I would say it's a fair 03:55</p> <p>2 statement if it's in the protocol. 03:55</p> <p>3 Q. If it's in the protocol. 03:55</p> <p>4 A. Yes. 03:55</p> <p>5 Q. And you have to have the circumstances 03:55</p> <p>6 that are called for by the protocol and that allow 03:55</p> <p>7 you to test that second sample; right? 03:55</p> <p>8 A. Yes 03:55</p> <p>9 Q. And you have to do an appropriate 03:55</p> <p>10 inspection or investigation and try to determine 03:55</p> <p>11 why the first sample tested out of specification; 03:56</p> <p>12 correct? 03:56</p> <p>13 A. Correct. Just for content uniformity 03:56</p> <p>14 for finished products, yes. 03:56</p> <p>15 Q. If you have an initial sample of the 03:56</p> <p>16 triplicate sample that tests out of specification, 03:56</p> <p>17 do you call that a blend failure? 03:56</p> <p>18 A. Do you want to say that again? 03:56</p> <p>19 MR. ANDERTON: Phil, would you read it 03:56</p> <p>20 back? 03:56</p> <p>21 (Whereupon, the testimony was read 03:56</p> <p>22 back by the court reporter, as recorded above) 03:56</p> <p>23 THE WITNESS: Potentially. 03:56</p> <p>24 BY MR. ANDERTON: 03:56</p> <p>25 Q. Potentially. 03:56</p>	<p>1 Q. Well, hold on one second. 03:57</p> <p>2 MS. DREWES: I don't want to interrupt, 03:57</p> <p>3 but on that hard drive that you -- that the 03:57</p> <p>4 witness gave, is it okay with everyone if we 03:57</p> <p>5 give everyone a CD attached with the documents 03:57</p> <p>6 rather than a hard copy? Because apparently 03:57</p> <p>7 you can't read them when they were printing. 03:57</p> <p>8 MR. ANDERTON: Yeah, that's acceptable to 03:58</p> <p>9 me. Mike, are you all right with that? 03:58</p> <p>10 MR. KERENSKY: Your voice was too faint 03:58</p> <p>11 for to me to hear your comment, ma'am. 03:58</p> <p>12 MS. DREWES: Would the hard drive that 03:58</p> <p>13 Dr. Bliesner gave us earlier, today, the -- we 03:58</p> <p>14 can print the -- we can print the documents 03:58</p> <p>15 but they are not legible, some of them, when 03:58</p> <p>16 we print them. For some reason they come out 03:58</p> <p>17 really dark is what I'm told. 03:58</p> <p>18 So if we can just give everyone a disc if 03:58</p> <p>19 that's agreeable to you. 03:58</p> <p>20 MR. ANDERTON: Are you okay with that, 03:58</p> <p>21 Mike? 03:58</p> <p>22 MS. DREWES: Apparently you can read it 03:58</p> <p>23 on the disc or on the computer screen. 03:58</p> <p>24 MR. KERENSKY: Just as long as a general, 03:58</p> <p>25 average, normal, everyday computer will open 03:58</p>
Page 291	Page 293
<p>1 A. Yes. 03:56</p> <p>2 Q. But if you have a protocol that allows 03:56</p> <p>3 you to test the second or third sample after 03:56</p> <p>4 conducting an appropriate investigation and after 03:56</p> <p>5 following the protocol properly -- 03:56</p> <p>6 A. Uh-huh. 03:56</p> <p>7 Q. -- that first out of specification 03:56</p> <p>8 result is not a blend failure, am I correct? 03:56</p> <p>9 A. If it meets the protocol, that is 03:56</p> <p>10 correct. 03:56</p> <p>11 Q. Okay. So you wouldn't call it a blend 03:56</p> <p>12 failure until you've run all the way to the end of 03:57</p> <p>13 the protocol -- 03:57</p> <p>14 A. Huh-huh. 03:57</p> <p>15 Q. -- is the way I'll describe that to you; 03:57</p> <p>16 is that correct? 03:57</p> <p>17 A. That's a fair way to put it. 03:57</p> <p>18 Q. Okay. Which might mean in certain 03:57</p> <p>19 circumstances until you've tested the third of the 03:57</p> <p>20 triplicate samples from one or more locations; 03:57</p> <p>21 right? 03:57</p> <p>22 A. Yes. 03:57</p> <p>23 Q. When you use the term -- and looking at 03:57</p> <p>24 Exhibit 108. 03:57</p> <p>25 A. Yes. 03:57</p>	<p>1 it, I'm happy. 03:58</p> <p>2 MR. ANDERTON: Well, that's just 03:58</p> <p>3 described my unit, so. 03:58</p> <p>4 BY MR. ANDERTON: 03:58</p> <p>5 Q. And then Dr. Bliesner, continuing on 03:58</p> <p>6 with this line of questioning, if you -- again if 03:58</p> <p>7 your protocol is appropriately drafted and you 03:59</p> <p>8 follow that factual progression that I just 03:59</p> <p>9 described, where you take samples of a blend and 03:59</p> <p>10 you test the first sample from a location and it 03:59</p> <p>11 is out of specification, then you follow the 03:59</p> <p>12 protocol and that results in you testing then the 03:59</p> <p>13 second sample from that location and it is within 03:59</p> <p>14 specification, it's okay to release that batch; 03:59</p> <p>15 right? 03:59</p> <p>16 A. If you're meeting your protocol. 03:59</p> <p>17 Q. If you have a protocol that allows for 03:59</p> <p>18 all of that, specifies it, and if you comply with 03:59</p> <p>19 it along the way; correct? 03:59</p> <p>20 A. That's a reasonable statement. 03:59</p> <p>21 Q. It's okay to release that batch? 03:59</p> <p>22 A. That blend, sure. 03:59</p> <p>23 Q. That -- 03:59</p> <p>24 A. Final blend in this case. 03:59</p> <p>25 Q. That initial I guess then -- correct. 03:59</p>

74 (Pages 290 to 293)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 294		Page 296	
1	So let me ask it another way. 03:59	1	documents that you reviewed -- if it's not listed 04:02
2	That initial out-of-specification result 04:00	2	in your report, it's not something you reviewed? 04:02
3	doesn't require that the entire blend and 04:00	3	A. Not necessarily. 04:02
4	therefore the entire batch be rejected. 04:00	4	Q. Pardon? 04:02
5	A. Not necessarily. 04:00	5	A. They're not mutually exclusive, most of 04:02
6	Q. Okay. 04:00	6	it because of all the volume of documents here. 04:02
7	A. It may be, you know, extraordinary 04:00	7	It obviously didn't include every single one that 04:02
8	circumstances where it comes in at 25 percent of 04:00	8	I reviewed, just ones that I felt had pertinent 04:02
9	assay or whatever, then it's a whole different 04:00	9	points with respect to this. 04:02
10	bailiwick. 04:00	10	Q. If it's not listed in your report -- 04:02
11	Q. Then your -- well, then your 04:00	11	A. Yes. 04:02
12	investigation your protocol provides for probably 04:00	12	Q. -- is it fair to say that you didn't 04:02
13	is going to reveal something other than just a 04:00	13	place any significance on it and didn't rely on it 04:02
14	single out-of-specification result? 04:00	14	in drafting your report? 04:02
15	A. More than likely, yes. 04:00	15	A. I didn't rely on it. I don't know if 04:02
16	Q. Okay. 04:00	16	significance is a word that I would use. 04:02
17	MR. KERENSKY: Are you guys still there? 04:00	17	Q. How are we to know or to identify if I 04:03
18	MR. ANDERTON: Yeah, we are here. 04:00	18	asked you right now whether you reviewed this SOP 04:03
19	MR. KERENSKY: Man, you got quiet. I 04:00	19	-- 04:03
20	thought you hung up on me. 04:00	20	A. Uh-huh 04:03
21	BY MR. ANDERTON: 04:00	21	Q. -- and it's not listed in your report -- 04:03
22	Q. Dr. Bliesner, when you did your paper 04:00	22	A. That's right. 04:03
23	audit of -- of this -- of Activis to prepare your 04:00	23	Q. -- how would you know? 04:03
24	report -- paper audit is your term not mine -- did 04:01	24	A. It's not listed in the report. I'd go 04:03
25	you ask for and did you receive the SOP of Activis 04:01	25	through this index and see if I popped it up. 04:03
Page 295		Page 297	
1	Totowa that provides the protocol for testing 04:01	1	Q. And if it's not in this index? 04:03
2	blend samples and retesting second or third 04:01	2	A. And it's not in the supplemental 04:03
3	samples if you have an initial 04:01	3	documents that were sent to me by -- then chances 04:03
4	out-of-specification result? 04:01	4	are I didn't review it. 04:03
5	A. I don't think I specifically asked for 04:01	5	Q. Okay. 04:03
6	that SOP. I remember reviewing an investigation 04:01	6	I'm going to hand you a document that has been 04:03
7	having to do with blend uniformity failure. 04:01	7	marked as -- well, what's it say on there? 04:03
8	Q. If you didn't ask for it, does that mean 04:01	8	A. 58. 04:03
9	you didn't review it either? 04:01	9	Q. 58? 04:04
10	A. I don't know if I could say that. I'd 04:01	10	A. Yeah. 04:04
11	have to go back and look at the paper at I 04:01	11	MR. ANDERTON: Plaintiffs' Exhibit 58. 04:04
12	reviewed. 04:01	12	Plaintiffs', Mike. 04:04
13	Q. Okay. 04:01	13	MR. KERENSKY: Got it. 04:04
14	A. With respect to that investigation. 04:01	14	BY MR. ANDERTON: 04:04
15	Q. The documents -- well, the documents 04:01	15	Q. Have you seen that before, Dr. Bliesner? 04:04
16	that you reviewed -- 04:02	16	A. Isn't this one that we -- the 483s that 04:04
17	A. Uh-huh. 04:02	17	were included before? Can I take a look at the 04:04
18	Q. -- are set forth in your report; right? 04:02	18	report? I'm pretty sure that I have, but I just 04:04
19	A. They should be, yes. 04:02	19	want to make sure. 04:04
20	Q. So if you reviewed it, our review of 04:02	20	Q. Well, if you didn't look at this, you 04:04
21	those documents will reveal that you reviewed it? 04:02	21	don't have a report. 04:04
22	A. That I reviewed it, yes. 04:02	22	A. Okay. 04:04
23	Q. Right. 04:02	23	Q. But you may do whatever you like to 04:04
24	A. That's a fair statement. 04:02	24	satisfy yourself, but I guess I can shortcircuit 04:04
25	Q. So if it's not listed among the 04:02	25	that. 04:04

75 (Pages 294 to 297)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 298			Page 300		
1	A. Okay. Please.	04:04	1	Q. Okay. Turn to page 43 of that document.	04:10
2	Q. Well, I'm here to help, Dr. Bliesner.	04:04	2	A. May have a second, please? I want to	04:10
3	Sarah will tell you I'm a giver.	04:05	3	make sure that I -- because there were some of	04:10
4	MS. DREWES: Oh, yeah. Big time.	04:05	4	these reports that didn't necessarily have all of	04:11
5	MR. KERENSKY: Note the snickers on the	04:05	5	the pages that came with them, the EIR. There was	04:11
6	phone.	04:05	6	one circumstance that I recall that didn't. So I	04:11
7	MR. ANDERTON: I'm sorry. Defense	04:05	7	want to make sure that what I've got over here is	04:11
8	Exhibit 58, Mike. I misspoke earlier.	04:05	8	the same and inclusive.	04:11
9	MR. KERENSKY: About you being a giving	04:05	9	Q. Okay.	04:11
10	person?	04:05	10	A. Okay. Is that fair?	04:11
11	MS. DREWES: Yeah, but got also about the	04:05	11	Q. Well, I guess I would hope that you	04:11
12	exhibit.	04:05	12	would have noted in your report when you reviewed	04:11
13	MR. KERENSKY: That you are here to	04:05	13	a document that was incomplete, but you didn't do	04:11
14	help? You're not with the IRS.	04:05	14	that with respect to this document.	04:11
15	MR. ANDERTON: It's Defendant's Exhibit	04:05	15	A. I just want to look at it.	04:11
16	58.	04:05	16	Q. Of course you do.	04:11
17	MR. KERENSKY: Thank you.	04:05	17	THE VIDEOGRAPHER: While he's doing that,	04:11
18	MR. ANDERTON: It's Plaintiffs' Exhibit	04:05	18	you have five minutes left on the tape.	04:11
19	90, I believe. No. Not true.	04:05	19	MR. ANDERTON: Let's go off the record	04:11
20	BY MR. ANDERTON:	04:05	20	and change the tape.	04:11
21	Q. Dr. Bliesner, did you review this or	04:05	21	THE WITNESS: The time is 4:13 p.m.	04:11
22	not. What do you think?	04:06	22	We're going off the record.	04:11
23	A. Yes.	04:09	23	(Short break)	04:21
24	Q. What page of your report are you looking	04:09	24	THE VIDEOGRAPHER: The time is 4:24 p.m.	04:21
25	at?	04:09	25	We are on the record. This is the beginning	04:22
Page 299			Page 301		
1	A. 47.	04:09	1	of tape eight.	04:22
2	Q. What reference?	04:09	2	BY MR. ANDERTON:	04:22
3	A. A37.	04:09	3	Q. Dr. Bliesner, are you all set?	04:22
4	Q. Well?	04:09	4	A. Yes, sir.	04:22
5	A. By the look of it.	04:09	5	Q. Okay. I want to ask you --	04:22
6	Q. That's an EIR, not a 483.	04:09	6	Dr. Bliesner, I'm going to go away from that	04:23
7	A. It is the EIR that had the 483s in	04:09	7	document for just a moment and ask you a general	04:23
8	them. I misspoke. I'm sorry.	04:09	8	question.	04:23
9	Q. So you didn't review this apparently?	04:09	9	A. Okay.	04:23
10	A. The 483s stand-alone?	04:09	10	Q. You are a chemist by trade; right?	04:23
11	Q. Yes.	04:09	11	A. I am a Ph.D. and analytical chemist by	04:23
12	A. No, it would be the EIR.	04:09	12	training.	04:23
13	Q. So that's Exhibit 91. You agree with	04:09	13	Q. Does that mean the answer to my question	04:23
14	that; right?	04:10	14	is yes?	04:23
15	A. Yes.	04:10	15	A. Chemist? Yes. Sorry. There are many	04:23
16	Q. All right. I'm going to hand you a copy	04:10	16	flavors of chemists. That's why.	04:24
17	of Exhibit 91.	04:10	17	Q. I understand, but above all else as a	04:24
18	A. Okay.	04:10	18	matter of fact you call yourself a chemist?	04:24
19	Q. So that we do this and keep you as	04:10	19	A. A research chemist, yes, I do.	04:24
20	comfortable as you need to be. I'm here for your	04:10	20	Q. When testing a tablet and particularly a	04:24
21	comfort.	04:10	21	solid oral dose tablet for potency --	04:24
22	I would like you to first look at the document	04:10	22	A. Uh-huh.	04:24
23	I just handed you and tell me if you reviewed that	04:10	23	Q. -- what method would you use if you	04:24
24	document.	04:10	24	could use any method you wanted?	04:24
25	A. 91. Plaintiffs' Exhibit 91, yes, sir.	04:10	25	A. Not to sound cryptic, but it depends on	04:24

76 (Pages 298 to 301)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

<p style="text-align: right;">Page 302</p> <p>1 the dosage form and what the characteristics are 04:24</p> <p>2 and what it's amenable to as far as analysis 04:24</p> <p>3 goes. 04:24</p> <p>4 Q. What do you mean by that? 04:24</p> <p>5 A. Well, it turns out that certain 04:24</p> <p>6 compounds might not be appropriately soluble let's 04:24</p> <p>7 say and therefore easily dissolved and injected 04:24</p> <p>8 into an HPLC system let's say. 04:24</p> <p>9 Q. Did you review the ANDA for Digoxin and 04:24</p> <p>10 particularly for the Digitek version of Digoxin 04:25</p> <p>11 tablets manufactured by Amide and then Activis 04:25</p> <p>12 sufficiently to allow you to have an opinion about 04:25</p> <p>13 which methods could be used to examine the potency 04:25</p> <p>14 of a tablet -- of one of those tablets? 04:25</p> <p>15 A. I'm sorry. Go again. 04:25</p> <p>16 MR. ANDERTON: Phil, can you get that? I 04:25</p> <p>17 did it very methodically. I would like 04:25</p> <p>18 Dr. Bliesner to hear that. I think I got it 04:25</p> <p>19 right. 04:25</p> <p>20 THE WITNESS: If I recall, I didn't get 04:26</p> <p>21 an opportunity to read all of the ANDA 04:26</p> <p>22 sections because I think that they were all 04:26</p> <p>23 available to me at the time of review. Just 04:26</p> <p>24 to put that in perspective. 04:26</p> <p>25 As far as being able to assess whether -- 04:26</p>	<p style="text-align: right;">Page 304</p> <p>1 Q. Okay. What about single point UV? How 04:27</p> <p>2 does that compare to HPLC as a test method to test 04:27</p> <p>3 the potency of a tablet and specifically of one of 04:27</p> <p>4 these Digitek Digoxin tablets? 04:27</p> <p>5 A. Single point UV? 04:27</p> <p>6 Q. Yes. 04:27</p> <p>7 A. How would it compare? It depends 04:27</p> <p>8 because LC is a separations technique that 04:27</p> <p>9 separates out any potential interference from the 04:27</p> <p>10 main component so you get an assay. An HPLC 04:27</p> <p>11 system essentially a UV system at the end. The 04:27</p> <p>12 detector for HPLC is just a UV. But in this case 04:28</p> <p>13 it is has, if you will, as an analogy, the HPLC is 04:28</p> <p>14 a means of preparing the sample so you're looking 04:28</p> <p>15 at a single component when it goes into the UV 04:28</p> <p>16 detector; okay? If you have -- it is possible 04:28</p> <p>17 with a product to develop and validate a method, 04:28</p> <p>18 single point UV method if there are no 04:28</p> <p>19 interferences. 04:28</p> <p>20 Q. If somebody sent you a sample -- 04:28</p> <p>21 A. Uh-huh. 04:28</p> <p>22 Q. -- and said Dr. Bliesner, chemist -- 04:28</p> <p>23 Ph.D. Chemist Bliesner, we'd like you to examine 04:28</p> <p>24 this tablet for potency. 04:28</p> <p>25 A. Uh-huh. 04:28</p>
<p style="text-align: right;">Page 303</p> <p>1 I guess the question is assess whether the 04:26</p> <p>2 methods are appropriate for use? 04:26</p> <p>3 BY MR. ANDERTON: 04:26</p> <p>4 Q. No. Do you have an opinion about -- 04:26</p> <p>5 about which of those -- which of the available 04:26</p> <p>6 methods to test a tablet for potency could be 04:26</p> <p>7 used? 04:26</p> <p>8 A. Could be used with -- HPLC is a method 04:26</p> <p>9 of choice. 04:26</p> <p>10 Q. Okay. 04:26</p> <p>11 A. If I'm not mistaken, having looking at 04:26</p> <p>12 the 484 stuff, those were HPLC methods for assays 04:26</p> <p>13 and related compounds. 04:26</p> <p>14 Q. And the Activis analytical method was 04:26</p> <p>15 also HPLC methods; correct? 04:26</p> <p>16 A. I'm pretty sure yes, yes. 04:27</p> <p>17 Q. So unless nobody knew what they were 04:27</p> <p>18 doing, HPLC was an acceptable method to test this 04:27</p> <p>19 compound; correct? 04:27</p> <p>20 A. For assay. 04:27</p> <p>21 Q. For assay. 04:27</p> <p>22 A. Correct. 04:27</p> <p>23 Q. Well, and to go back to the term I used, 04:27</p> <p>24 for potency. 04:27</p> <p>25 A. Yes. Assay, potency, same thing. 04:27</p>	<p style="text-align: right;">Page 305</p> <p>1 Q. How would you compare the reliability of 04:28</p> <p>2 results of a test conducted using single point UV 04:28</p> <p>3 versus a test using HPLC? 04:29</p> <p>4 A. How would you compare? 04:29</p> <p>5 Q. How would you compare? Not literally 04:29</p> <p>6 how would you put them side by side and compare. 04:29</p> <p>7 How would you characterize the differences between 04:29</p> <p>8 results reached using single point UV versus the 04:29</p> <p>9 results reached using HPLC. Is one more reliable 04:29</p> <p>10 than the other? 04:29</p> <p>11 A. Not necessarily. It depends on whether 04:29</p> <p>12 there are interference issues. You've got to 04:29</p> <p>13 realize that HPLC with a UV detector is a single 04:29</p> <p>14 point UV detection, just like you put it into a UV 04:29</p> <p>15 spectrometer. Same thing. It's only a single 04:29</p> <p>16 point. 04:29</p> <p>17 Q. So you need to know more about the 04:29</p> <p>18 circumstances before you would be able to -- 04:29</p> <p>19 A. Absolutely. Sure. 04:29</p> <p>20 Q. Be able to compare the reliability of 04:29</p> <p>21 outcomes for -- 04:29</p> <p>22 A. Right. 04:29</p> <p>23 Q. -- those two tests. 04:29</p> <p>24 A. For instance, they do dissolution 04:29</p> <p>25 testing. And the dissolution method is UV, but 04:29</p>

77 (Pages 302 to 305)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 306	Page 308
<p>1 there is a whole -- if I recall correctly, pulling 04:29</p> <p>2 off memory -- there is a derivatization and things 04:30</p> <p>3 that like that with respect to the UV because that 04:30</p> <p>4 would suggest that there are potential 04:30</p> <p>5 interferences. And derivatization and looking at 04:30</p> <p>6 it in the means that they did would suggest -- not 04:30</p> <p>7 having looked at the validation -- that they were 04:30</p> <p>8 able to get around interferences in that fashion. 04:30</p> <p>9 Q. Just to be clear with respect to 04:30</p> <p>10 Activis, are the entirety of your opinions in this 04:30</p> <p>11 case set forth in the report you've issued? Do 04:31</p> <p>12 you have any supplemental or additional opinions 04:31</p> <p>13 with respect to Activis? 04:31</p> <p>14 A. I don't believe so. 04:31</p> <p>15 Q. Well, you don't believe so or you don't? 04:31</p> <p>16 A. It's a broad statement. 04:31</p> <p>17 Q. I need this question to be answered 04:31</p> <p>18 definitively, Dr. Bliesner. It's a very important 04:31</p> <p>19 question. 04:31</p> <p>20 A. Additional, post-the-report? 04:31</p> <p>21 Q. Yes. 04:31</p> <p>22 A. In the report? 04:31</p> <p>23 Q. Yeah, you have issued a report in this 04:31</p> <p>24 case -- 04:31</p> <p>25 A. Yes. 04:31</p>	<p>1 your report? 04:32</p> <p>2 A. I've not reviewed any documentation or 04:32</p> <p>3 anything else that would supplement what I've 04:32</p> <p>4 written in the report. 04:32</p> <p>5 Q. So again need this answered my way. You 04:32</p> <p>6 don't have any supplemental opinions about Activis 04:32</p> <p>7 that are not contained in this report; is that a 04:32</p> <p>8 correct statement? 04:32</p> <p>9 A. That is a correct statement. 04:33</p> <p>10 Q. Thank you. 04:33</p> <p>11 So the process -- well, you -- the product 04:33</p> <p>12 that was in the market and subject to recall you 04:33</p> <p>13 know was .125 and .25 milligram Digitek. You are 04:33</p> <p>14 aware of that; right? 04:33</p> <p>15 A. Yes, sir. 04:33</p> <p>16 Q. Two dose strengths; right? 04:33</p> <p>17 A. Yes, sir. 04:33</p> <p>18 Q. And both processes were validated; 04:33</p> <p>19 correct? 04:33</p> <p>20 A. I have not seen the process validation 04:33</p> <p>21 reports so I can't say definitively, but because 04:34</p> <p>22 they're in the application and it was approved, 04:34</p> <p>23 one would extrapolate that they were validated. 04:34</p> <p>24 Q. Any reason to believe that either 04:34</p> <p>25 process was not validated? 04:34</p>
Page 307	Page 309
<p>1 Q. -- that we've been told contains your 04:31</p> <p>2 opinions -- 04:31</p> <p>3 A. Yes. 04:31</p> <p>4 Q. -- about Activis. And there was some 04:31</p> <p>5 exchange last time about whether you had an 04:31</p> <p>6 opinion about Mylan or didn't have an opinion and 04:31</p> <p>7 we got a representation from Plaintiffs' counsel 04:31</p> <p>8 about that, and that issue is done and resolved as 04:31</p> <p>9 far as we're concerned. 04:31</p> <p>10 A. Okay. 04:31</p> <p>11 Q. So I'm asking you now strictly about 04:31</p> <p>12 Activis and the opinions that are set forth in 04:32</p> <p>13 your June 15, 2010, report. 04:32</p> <p>14 A. Yes. 04:32</p> <p>15 Q. About Activis. 04:32</p> <p>16 A. Yes. 04:32</p> <p>17 Q. Do they -- do they comprise the entirety 04:32</p> <p>18 of your opinions about Activis in this case? 04:32</p> <p>19 A. That's a fair statement, yes. 04:32</p> <p>20 Q. Yes, they do? 04:32</p> <p>21 A. Uh-huh. 04:32</p> <p>22 Q. You need to say that. 04:32</p> <p>23 A. Yes, they do. 04:32</p> <p>24 Q. Okay. So there are no supplemental 04:32</p> <p>25 opinions about Activis that are not contained in 04:32</p>	<p>1 A. No. 04:34</p> <p>2 Q. And I believe you testified last time 04:34</p> <p>3 that you're not an expert in process validation 04:34</p> <p>4 but that you certainly support -- I believe those 04:34</p> <p>5 were your words. 04:34</p> <p>6 A. Yes. 04:34</p> <p>7 Q. From an -- I forget what perspective you 04:34</p> <p>8 said. 04:34</p> <p>9 A. Cross-functional and analytical 04:34</p> <p>10 development testing, troubleshooting. 04:34</p> <p>11 Q. That's a fancy way of saying you 04:34</p> <p>12 recognize the value and importance of process 04:34</p> <p>13 validation. 04:34</p> <p>14 A. I absolutely, yeah. 04:34</p> <p>15 Q. Okay. 04:34</p> <p>16 A. It's a very critical component to the 04:34</p> <p>17 whole application development. 04:34</p> <p>18 Q. It's kind of a jumping off point for 04:34</p> <p>19 everything, isn't it? 04:34</p> <p>20 A. Process validation? 04:34</p> <p>21 Q. Yes. 04:34</p> <p>22 A. Jumping off point? 04:34</p> <p>23 Q. Well, with respect actually producing 04:34</p> <p>24 and manufacturing a drug product. 04:34</p> <p>25 A. Uh-huh. 04:34</p>

78 (Pages 306 to 309)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 310			Page 312		
1	Q. You must first develop and validate a	04:34	1	manufacturing product within specification over	04:37
2	process for doing that; correct?	04:35	2	time; correct?	04:37
3	A. If you need to develop and validate --	04:35	3	A. That's one aspect; correct. You also	04:37
4	develop a dosage form, a formulation and then to a	04:35	4	monitor complaints, returns, you know,	04:37
5	small scale move it into process validation,	04:35	5	investigations, that come up during the course of	04:37
6	that's correct.	04:35	6	the manufacturing. Lots of different things.	04:37
7	Q. Okay. So once you have a formulation	04:35	7	Q. Understood.	04:37
8	developed --	04:35	8	You continue to monitor the things that might	04:37
9	A. Yes.	04:35	9	call into question the validation of your process;	04:37
10	Q. -- the next step is to develop and	04:35	10	right?	04:37
11	validate the process; right?	04:35	11	A. That's correct. Because in my	04:37
12	A. Scale up first and then validate.	04:35	12	experience when you go from scale up to	04:37
13	Q. Okay. So let's make that the not the	04:35	13	manufacturing, invariably as you gain experience	04:37
14	next immediate step after developing the	04:35	14	with the product there, you'll find things that	04:37
15	formulation but two steps later is a process	04:35	15	are potentially difficult.	04:37
16	validation. And you cannot go forward with	04:35	16	Q. And finding things that are potential	04:37
17	manufacturing any drug product without a validated	04:35	17	difficulties, to use your words?	04:37
18	process; is that correct?	04:35	18	A. Uh-huh.	04:37
19	A. That's correct.	04:35	19	Q. That doesn't mean your process is	04:37
20	Q. The FDA would not approve either an NDA	04:35	20	invalidated. It means you need to investigate and	04:37
21	or an ANDA without demonstration of a validated	04:35	21	determine whether they require an adjustment of	04:37
22	process; correct?	04:35	22	your process; right?	04:38
23	A. And the demonstration would be for	04:35	23	A. That's open to interpretation. It	04:38
24	instance in the ANDA III production run.	04:35	24	really is. And the agency, you know, in one	04:38
25	Q. Understood.	04:35	25	circumstance may say your process is out of	04:38
Page 311			Page 313		
1	A. That's the output of process validation	04:35	1	control, it's invalidated, but in another	04:38
2	specifically requiring, you know, a validation,	04:36	2	circumstance the same people within the same	04:38
3	reported development on the application, that	04:36	3	division may say, you know, it's okay. You need	04:38
4	isn't necessarily the case.	04:36	4	to put in some additional controls. So it's open	04:38
5	Q. In whatever form, you must prove to the	04:36	5	to interpretation.	04:38
6	FDA --	04:36	6	Q. What weight do you give -- in validating	04:38
7	A. Uh-huh.	04:36	7	as you're undertaking a consulting engagement --	04:38
8	Q. -- that you have developed and validated	04:36	8	A. Uh-huh.	04:38
9	your process before they will approve your	04:36	9	Q. -- and evaluating whether your client	04:38
10	application.	04:36	10	has or is achieving GMP compliance?	04:38
11	A. Yes.	04:36	11	A. Uh-huh.	04:38
12	Q. Is that correct?	04:36	12	Q. What weight do you give to the fact that	04:38
13	A. That is correct.	04:36	13	the client has a validated process followed by	04:38
14	Q. All right. And a process validation	04:36	14	years and years and production of literally	04:38
15	tells you that you have developed a process that	04:36	15	billions and billions of tablets that were within	04:38
16	allows you to consistently manufacture product	04:36	16	specification?	04:39
17	within specification; right?	04:36	17	A. I'm sorry. It was a long one, so --	04:39
18	A. Within the operating parameters of the	04:36	18	MR. ANDERTON: Please read it back.	04:39
19	equipment; correct.	04:36	19	(Whereupon, the testimony was read	04:39
20	Q. Understood.	04:36	20	back by the court reporter, as recorded above)	04:39
21	A. Uh-huh.	04:36	21	THE WITNESS: That's obviously an	04:39
22	Q. And as you move forward from your	04:36	22	important part of the picture.	04:39
23	process validation, there are various things that	04:36	23	BY MR. ANDERTON:	04:39
24	speak to or that confirm the conclusions reached	04:36	24	Q. Okay.	04:39
25	in your process validation study, one of which is	04:36	25	A. Supporting process validation and	04:39

79 (Pages 310 to 313)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 314			Page 316		
1	showing you're in control.	04:39	1	A. No.	04:41
2	Q. Okay. So that is a significant fact	04:39	2	Q. -- what the heck are you talking about?	04:41
3	that -- as you did an evaluation of circumstances	04:39	3	A. I understand.	04:41
4	that met those -- that description, that would be	04:39	4	Q. Okay.	04:41
5	one piece of information that you put in, in the	04:39	5	A. I just want to make sure that we're on	04:41
6	bucket if you will, suggesting GMP compliance.	04:39	6	all on the same page here. It's late in the day	04:41
7	A. One piece. Manufacturing investigations	04:39	7	and I'm not trying to be evasive.	04:41
8	would go hand and hand with that in particular.	04:39	8	Q. I understand but as I understood your	04:41
9	Q. Understood. But that fact that I've	04:39	9	answer, if you were going to question or challenge	04:41
10	described --	04:40	10	the data -- you said assuming the data.	04:41
11	A. Uh-huh.	04:40	11	A. Are valid.	04:41
12	Q. -- validated process and years of	04:40	12	Q. Valid.	04:41
13	in-specification production covering billions of	04:40	13	A. Your reflection of what's reality.	04:41
14	tablets, that would go certainly go in the --	04:40	14	Q. Exactly.	04:41
15	A. It would. We're assuming that the data	04:40	15	A. Uh-huh.	04:41
16	reporting capture and all that stuff is accurate.	04:40	16	Q. The only way you could determine whether	04:41
17	Q. Understood.	04:40	17	the data are valid is to start by looking at the	04:41
18	A. Okay. That's a big assumption because	04:40	18	data. There would be other steps you perform, but	04:41
19	it isn't necessarily the case in a lot of	04:40	19	the first step you'd have to do is look at the	04:41
20	facilities.	04:40	20	data, am I correct?	04:41
21	Q. Okay.	04:40	21	A. That's correct.	04:41
22	A. Uh-huh.	04:40	22	Q. Look at page 16 of your report, please.	04:42
23	Q. But you would only be able to determine	04:40	23	A. Yes.	04:42
24	whether it was accurate if you looked at the	04:40	24	Q. Give me one second.	04:42
25	data.	04:40	25	A. Sure.	04:42

Page 315			Page 317		
1	A. You'd have to look at the data and then	04:40	1	Q. Dr. Bliesner, paragraph 39 on page 16.	04:43
2	confirm with individuals that are doing entry into	04:40	2	Do you see that?	04:43
3	the system, or validation of the system and	04:40	3	A. Yes, sir. I do.	04:43
4	whatever.	04:40	4	Q. There you discuss investigation into --	04:43
5	Q. Understood.	04:40	5	well, you don't identify the lot number, but --	04:43
6	A. That they would hold up. I'm sorry.	04:40	6	A. No, sir.	04:43
7	No. Would hold up.	04:40	7	Q. But the lot that had some defectively	04:43
8	Q. But inherent in what you've just said --	04:40	8	thick tablets discovered during manufacturing.	04:43
9	A. Uh-huh.	04:40	9	And the second to last sentence says:	04:43
10	Q. -- is that you must look at the data in	04:40	10	"Product is released to market without	04:43
11	order to challenge it; correct?	04:40	11	conclusive evidence of what caused the	04:43
12	A. The data in a broad sense.	04:40	12	double-thick problem on 5 December, 2007."	04:43
13	Q. You used that term, Dr. Bliesner.	04:40	13	That's not accurate is it?	04:43
14	A. Yes, I know. But if we are talking	04:40	14	A. I'd have to go back and pull up the	04:43
15	specific process validation, methods validation,	04:41	15	reference to be sure.	04:43
16	data in general because the data can be -- I'm	04:41	16	Q. Okay. Well you --	04:43
17	sorry.	04:41	17	A. Because it's very -- the investigation,	04:43
18	Q. As you used the term?	04:41	18	if I recall how it's done and how it's written,	04:43
19	A. Yes.	04:41	19	anything like that, it was stuff to pull dates	04:43
20	Q. I was merely trying to ask you questions	04:41	20	together so I can't definitively say that that's	04:43
21	about how you --	04:41	21	an incorrect date.	04:43
22	A. Okay.	04:41	22	Q. Well there's -- if you read the	04:43
23	Q. -- used the term?	04:41	23	investigation record, there's plenty of documents	04:43
24	A. Okay.	04:41	24	in the investigation report indicating activities	04:44
25	Q. Now, you can't use it and then say --	04:41	25	occurring. In fact the 100 percent visual	04:44

80 (Pages 314 to 317)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 318	Page 320
<p>1 inspection very clearly didn't occur until January 04:44</p> <p>2 2008. 04:44</p> <p>3 A. Okay. 04:44</p> <p>4 Q. So did you just misread that 04:44</p> <p>5 investigation? 04:44</p> <p>6 A. Incident report. I'm sorry. What is 04:44</p> <p>7 the question? 04:44</p> <p>8 Q. Did you just misread that investigative 04:44</p> <p>9 report? 04:44</p> <p>10 A. I don't think so. Like I said, I have 04:44</p> <p>11 to go back and look at it and reconstruct it again 04:44</p> <p>12 to determine if that -- your claim that that's an 04:44</p> <p>13 incorrect date is incorrect. 04:44</p> <p>14 Q. You made comment earlier about operators 04:44</p> <p>15 or employees being unable to read or speak English 04:45</p> <p>16 or cannot read English. 04:45</p> <p>17 A. Uh-huh. 04:45</p> <p>18 Q. What did you do to verify the accuracy 04:46</p> <p>19 of that statement? 04:46</p> <p>20 A. I -- if I'm not mistaken, it was in an 04:46</p> <p>21 e-mail and I read the e-mail. 04:46</p> <p>22 Q. So you just read the e-mail and that was 04:46</p> <p>23 enough for you? 04:46</p> <p>24 A. Yes. 04:46</p> <p>25 Q. Okay. So you didn't do anything beyond 04:46</p>	<p>1 Q. Okay. And you understand, then, that 04:47</p> <p>2 the lawyers for the Plaintiffs as part of 04:47</p> <p>3 performing their job are going to go out and find 04:47</p> <p>4 documents that they believe support their 04:47</p> <p>5 position. 04:47</p> <p>6 A. I would say that's a fair statement. It 04:48</p> <p>7 would make sense. 04:48</p> <p>8 Q. Reasonably self-evident; right? 04:48</p> <p>9 A. Yeah, it makes sense. 04:48</p> <p>10 Q. Okay. And when you got the documents 04:48</p> <p>11 from Plaintiffs' counsel in this case, I see two 04:48</p> <p>12 primary lists of documents that you got. One is 04:48</p> <p>13 Plaintiffs' exhibits. 04:48</p> <p>14 A. Uh-huh. 04:48</p> <p>15 Q. And the other Mylan exhibits. 04:48</p> <p>16 A. Uh-huh. 04:48</p> <p>17 Q. Did it trouble you at all that you were 04:48</p> <p>18 looking only at the documents that Plaintiffs' 04:48</p> <p>19 counsel wanted to you see? 04:48</p> <p>20 A. I don't think that's necessarily the way 04:48</p> <p>21 it was. In particular I asked at the start of the 04:48</p> <p>22 project for a list of -- again, go back to my 04:48</p> <p>23 report. I was serving as a consultant, and they 04:48</p> <p>24 asked me to evaluate the status of, you know, the 04:48</p> <p>25 facility in terms of manufacturing restricted to 04:48</p>
Page 319	Page 321
<p>1 that? 04:46</p> <p>2 A. I'm not sure what I could have done 04:46</p> <p>3 beyond that, quite honestly. 04:46</p> <p>4 Q. Dr. Bliesner, do you understand the 04:46</p> <p>5 nature of litigation? You've never been an expert 04:46</p> <p>6 witness before. 04:46</p> <p>7 A. I have not. 04:46</p> <p>8 Q. Do you understand the general nature of 04:46</p> <p>9 litigation? 04:46</p> <p>10 A. The general nature of litigation? 04:46</p> <p>11 Q. Yeah. 04:46</p> <p>12 A. How you would define it and how I define 04:46</p> <p>13 it, probably different things. 04:46</p> <p>14 Q. Well, do you understand that Plaintiffs 04:46</p> <p>15 are the ones who bring lawsuits and they make 04:47</p> <p>16 allegations against Defendants. They allege that 04:47</p> <p>17 certain things happened and in this context -- 04:47</p> <p>18 pharmaceutical product liability context -- 04:47</p> <p>19 Plaintiffs allege that they were harmed by 04:47</p> <p>20 products; right? 04:47</p> <p>21 A. That's correct, yes. 04:47</p> <p>22 Q. And you understand that the lawyers for 04:47</p> <p>23 the Plaintiffs are required to or are attempting 04:47</p> <p>24 to prove those allegations. 04:47</p> <p>25 A. That's correct, as I understand it. 04:47</p>	<p>1 Digitek, restricted to Amide, Activis, or 04:49</p> <p>2 whatever, and then they then asked me if there 04:49</p> <p>3 were documents that I thought would be useful for 04:49</p> <p>4 my review so I created the list and gave it to 04:49</p> <p>5 them. 04:49</p> <p>6 Q. You did? 04:49</p> <p>7 A. Yes. 04:49</p> <p>8 Q. Do we have that list? 04:49</p> <p>9 A. It was given the last go around. I 04:49</p> <p>10 handed it out, or it was on the disc, one of the 04:49</p> <p>11 two. 04:49</p> <p>12 Q. Well, the only thing you gave last go 04:49</p> <p>13 around was Exhibits -- you have them there in 04:49</p> <p>14 front of you, 107, 108? 04:49</p> <p>15 A. Uh-huh. It may be on that hard drive. 04:49</p> <p>16 It was provided. 04:49</p> <p>17 Q. Okay. And when did you prepare that 04:49</p> <p>18 list that you gave to Plaintiffs? 04:49</p> <p>19 A. Very early on in the process. 04:49</p> <p>20 Q. Did you get the documents that were on 04:49</p> <p>21 that list? 04:49</p> <p>22 A. Not all of them, no. 04:49</p> <p>23 Q. Did that trouble you at all? 04:49</p> <p>24 A. Trouble is not a word. It was a little 04:49</p> <p>25 frustrating for me. 04:50</p>

81 (Pages 318 to 321)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 322			Page 324		
1	Q. What didn't you get?	04:50	1	Q. Is it not fair wholly or is it not fair	04:51
2	A. I would have to look at the list	04:50	2	just partially. I mean you got all the documents	04:51
3	specifically. I think like we talked about, I got	04:50	3	they wanted you to have but did not get the	04:51
4	late yesterday evening -- was it process	04:50	4	documents, all of the documents you asked for.	04:51
5	validation report, you know, those kinds of	04:50	5	A. That's a true statement.	04:51
6	things. I know there were difficulties with the	04:50	6	Q. Okay.	04:51
7	system from my understanding.	04:50	7	A. And why that happened, I'm not sure.	04:52
8	Q. Okay.	04:50	8	Other than it was --	04:52
9	A. In getting documents and they're not all	04:50	9	Q. Got a guess?	04:52
10	loaded up and that kind of stuff.	04:50	10	A. No. Remember rule number one, don't	04:52
11	Q. Okay.	04:50	11	guess.	04:52
12	A. So.	04:50	12	Q. I understand. I understand.	04:52
13	Q. Well, so what didn't you get?	04:50	13	A. And that's what so much of this has been	04:52
14	A. I would have to pull up the list.	04:50	14	today is that I'm trying to make sure that I'm not	04:52
15	Q. But there were things that you asked for	04:50	15	guessing.	04:52
16	and didn't get.	04:50	16	Q. I don't want you to guess.	04:52
17	A. That's correct.	04:50	17	A. Yes.	04:52
18	Q. You definitely got all of the	04:50	18	Q. But you're a sharp guy. I'm sure you	04:52
19	Plaintiffs' exhibits, though; right?	04:50	19	can figure out why it is that you got what they	04:52
20	A. I -- I can't say whether I got all the	04:50	20	wanted you to have but didn't get everything you	04:52
21	Plaintiffs' exhibits.	04:50	21	asked for.	04:52
22	Q. Well?	04:50	22	A. I wouldn't comment on that.	04:52
23	A. If they are all of them, I, then, yes.	04:50	23	Q. Does it trouble you at all Dr. Bliesner	04:52
24	But I don't know if that's all of them. Because	04:50	24	that nobody has produced a single double-thick	04:53
25	we -- they created as I understand -- excuse me.	04:50	25	tablet from the market from the recalled batches?	04:53
Page 323			Page 325		
1	They created folders that individuals could look	04:50	1	A. Trouble?	04:53
2	at.	04:50	2	Q. You're a GMP compliance expert. You've	04:53
3	Q. Individual whos? I mean.	04:50	3	conducted \$140,000's worth of analysis here,	04:54
4	A. People like myself that were reviewing	04:51	4	reaching the conclusion that you think adulterated	04:54
5	documents.	04:51	5	product reached the market, yet no one has	04:54
6	Q. Okay.	04:51	6	produced a double-thick tablet from the recalled	04:54
7	A. And those documents that they wished me	04:51	7	batches in almost three years since the recall.	04:54
8	to review were placed in folders on their	04:51	8	A. They have not. That's a fact.	04:54
9	electronic system or they delivered them, sent,	04:51	9	Q. That's a fact?	04:54
10	e-mail -- e-mailed them.	04:51	10	A. Okay. I take you at your word.	04:54
11	Q. Okay.	04:51	11	Q. That's a fact. Does that trouble you?	04:54
12	A. Uh-huh.	04:51	12	A. Trouble is not a word that I would use;	04:54
13	Q. And did you understand as you conducted	04:51	13	okay?	04:54
14	your paper audit that the Plaintiffs' exhibits	04:51	14	Q. Does it have any impact on the way you	04:54
15	were the documents the Plaintiffs' lawyers	04:51	15	think about your engagement or about on the	04:54
16	believed helped them?	04:51	16	conclusions that you you've reached?	04:54
17	A. Actually I didn't give it any	04:51	17	A. No, not necessarily. Even though again	04:54
18	consideration. I was just doing an audit.	04:51	18	we've established I'm not a recall expert.	04:54
19	Q. Never occurred to you?	04:51	19	Recalls are not a science -- let's put it that	04:54
20	A. Actually, it did not.	04:51	20	way -- and we've already established that there	04:54
21	Q. Well, you weren't necessarily doing an	04:51	21	are a large number.	04:55
22	audit. You were looking at the documents they	04:51	22	Q. 680 million.	04:55
23	selected to give you.	04:51	23	A. Billion I think is what Mr. Moriarty	04:55
24	A. I don't think that's a -- that's fair	04:51	24	said last go around.	04:55
25	statement.	04:51	25	Q. Subject to the recall, 680 million. In	04:55

82 (Pages 322 to 325)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 326		Page 328	
1	fact Plaintiff told you that in your meeting 04:55	1	in anything. 04:57
2	before your deposition. 04:55	2	MR. ANDERTON: Mike, the problem is, he 04:57
3	A. Yes, sir. That -- 04:55	3	answered my question. He recognized -- 04:57
4	Q. And -- 04:55	4	MR. KERENSKY: There's just disagreement. 04:57
5	A. -- a small number of a large number is 04:55	5	MR. ANDERTON: He recognized -- Mike, he 04:57
6	still substantial in my mind. 04:55	6	recognized and stopped himself when he was 04:57
7	Q. Zero is not substantial, is it? 04:55	7	answering a question that hadn't been asked. 04:57
8	A. Just because you haven't seen anything 04:55	8	He did it. 04:57
9	doesn't mean it's not there, especially when you 04:55	9	MR. KERENSKY: Well, I don't how he could 04:57
10	look at the lack of controls within that facility. 04:55	10	be doing both, Mike. He was still talking and 04:57
11	Q. You're relying on inferences again; 04:55	11	you interrupted him. That's all there is to 04:57
12	right? 04:55	12	it. 04:57
13	A. I don't think it's inferences. 04:55	13	MR. ANDERTON: I didn't interrupt him, 04:57
14	Q. You don't have any direct proof so it 04:55	14	Mike. Now, I really don't appreciate this -- 04:57
15	must be an inference; right? 04:55	15	I mean you are telling him what to do, Mike. 04:57
16	A. I don't think an inference. It's a mass 04:55	16	It's inappropriate. 04:57
17	of data. I think that the thing that troubles me 04:55	17	MR. KERENSKY: I'm telling you what to 04:57
18	more than anything -- I'm sorry. I'm done. 04:56	18	do. Don't interrupt him. 04:58
19	Q. It's a mass of data that create an 04:56	19	MR. ANDERTON: Dr. Bliesner, are you 04:58
20	inference. 04:56	20	done? 04:58
21	MR. KERENSKY: There you go again, Mike. 04:56	21	MR. KERENSKY: Read that whole answer 04:58
22	MR. ANDERTON: Mike, he stopped his 04:56	22	back before Mike started talking again and 04:58
23	answer and said I'm done. 04:56	23	then ask him that question and we'll move on. 04:58
24	MR. KERENSKY: He took a breath. 04:56	24	MR. ANDERTON: I asked him the question. 04:58
25	MR. ANDERTON: He said -- 04:56	25	He stopped himself, Mike. You're not here. 04:58
Page 327		Page 329	
1	MR. KERENSKY: And you jumped on him. 04:56	1	He put his hands up and said "I'm sorry." And 04:58
2	Let him finish. 04:56	2	he stopped and said -- 04:58
3	MR. ANDERTON: Mike, he said I'm done. 04:56	3	MR. KERENSKY: And you started to 04:58
4	MR. KERENSKY: Read it back. If you are 04:56	4	interrupt him. 04:58
5	right, I'll take it back. 04:56	5	MR. ANDERTON: Not true. Dr. Bliesner, 04:58
6	(Whereupon, the testimony was read 04:56	6	do you have anything to add to that answer? 04:58
7	back by the court reporter, as recorded above) 04:56	7	MR. KERENSKY: If you need to hear it 04:58
8	Q. Are you done, Dr. Bliesner? 04:56	8	read back to you, Dr. Bliesner, you may ask 04:58
9	A. On which point here? 04:56	9	for that. 04:58
10	Q. Exactly. 04:56	10	THE WITNESS: Read it back one more time, 04:58
11	MR. KERENSKY: Let's read back what he 04:56	11	please. 04:58
12	was saying when you jumped on his sentence 04:56	12	(Whereupon, the testimony was read back 04:59
13	there. 04:56	13	by the court reporter, as recorded above) 04:59
14	MR. ANDERTON: And I think the record 04:56	14	THE WITNESS: Was the fact that nobody 04:59
15	clearly showed earlier that he interrupted 04:56	15	ever tested double-thick tablets they found in 04:59
16	me. I let that go. Go ahead, Phil. 04:56	16	the facility. That's what I find troubling. 04:59
17	MR. KERENSKY: I think his last word was 04:57	17	BY MR. ANDERTON: 04:59
18	"and." 04:57	18	Q. Okay. But is that more -- 04:59
19	MR. ANDERTON: No, it wasn't. 04:57	19	MR. KERENSKY: Make your objection, Mike. 04:59
20	MR. KERENSKY: What was the last word 04:57	20	BY MR. ANDERTON: 04:59
21	before you said no, no. I couldn't quite hear 04:57	21	Q. Is that more troubling to you, 04:59
22	Phil. He was fairly far away. 04:57	22	Dr. Bliesner, than the fact that out of 680 04:59
23	MR. ANDERTON: The thing that tells me 04:57	23	million tablets, in three years nobody has 04:59
24	more than anything. 04:57	24	presented a single double-thick tablet? 04:59
25	MR. KERENSKY: You don't end a sentence 04:57	25	A. Absolutely because not testing on a 04:59

83 (Pages 326 to 329)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

Page 330		Page 332	
1	product that's clearly failed and identified had	04:59	1 questions.
2	failed is -- it really raises eyebrows. All kinds	04:59	2 Q. You don't have right to refuse to answer
3	of questions come up. Why didn't they? Is	04:59	3 that unless you -- unless it is truly privileged.
4	somebody hiding something? Have found things	04:59	4 Do you understand that?
5	before? Are they dumping it? These are just	04:59	5 A. I believe it's truly privileged between
6	questions that come to mind. I'm not suggesting	04:59	6 my doctor. Because I specifically asked that
7	--	04:59	7 because he asked me.
8	Q. All of --	04:59	8 Q. Were you seeking medical advice when you
9	A. -- all of these things. Just a whole	04:59	9 asked him these questions?
10	plethora of questions come into play when you	04:59	10 A. I was in for an appointment yes.
11	don't see -- it's happened several times as we	04:59	11 Q. Were you seeking medical advice when you
12	both recognize.	05:00	12 asked him questions about Digoxin?
13	Q. And the way to answer those questions	05:00	13 A. When I asked him questions about it? I
14	would be to take them and dive into the	05:00	14 didn't ask him questions. He volunteered.
15	manufacturing and production records for that	05:00	15 Q. How did he come to volunteer?
16	product.	05:00	16 A. I'm not comfortable talking about this.
17	A. No, that's not true.	05:00	17 Q. I'm not asking for the substance
18	Q. Or for any other product.	05:00	18 A. I'm not comfortable talking about it.
19	A. That's not true. They didn't collect	05:00	19 Q. You don't have a choice.
20	the samples and test them.	05:00	20 MR. KERENSKY. Mike, maybe I can settle
21	Q. The way --	05:00	21 this. No one is going to ask this witness to
22	A. In my experience -- in my experience	05:00	22 tell any jury what his doctor said about
23	with respect to batch records, okay, personal	05:00	23 Digitek. I will stipulate to that right now.
24	experience, recent personal experience, batch	05:00	24 MR. ANDERTON: Well, we're going to ask
25	records don't necessarily reflect reality. I've	05:00	25 this witness what his doctor told him so we
Page 331		Page 333	
1	had a client in the last year that manufactures	05:00	1 know whether it formed part of the basis for
2	product and doesn't even look at the batch record	05:00	2 his expert opinion in this case.
3	because it isn't written where you can follow it.	05:00	3 THE WITNESS: It was after the fact. I
4	They just go out there and wing it on the floor.	05:00	4 will tell you that.
5	So just because you got a batch record doesn't	05:00	5 BY MR. ANDERTON:
6	mean that that's gospel what's happening on the	05:00	6 Q. You are still subject to testifying,
7	floor. That's my personal experience.	05:00	7 Dr. Bliesner.
8	Q. Did you throw your medicine from that	05:00	8 MR. KERENSKY: You have a right to
9	manufacturer away? They're not following their	05:00	9 protect your conversations between you and
10	batch records. Did you go run up to your medicine	05:00	10 your doctor. And you've got two
11	cabinet and throw that away?	05:00	11 countervailing opinions from two lawyers,
12	A. It's not appropriate.	05:00	12 neither of which represent you. You got to
13	Q. What do you mean it's not appropriate?	05:01	13 make the call, doctor.
14	A. Because it's not a solid oral dosage for	05:01	14 BY MR. ANDERTON:
15	me.	05:01	15 Q. Dr. Bliesner, you know what you're doing
16	Q. Dr. Bliesner, last time you talked	05:01	16 here. You're setting yourself up to be brought
17	about, you gave some testimony about conversation	05:01	17 back for another session of deposition.
18	you had with your doctor regarding this subject,	05:01	18 A. So be it. I am not comfortable sharing
19	the subject of this litigation. And I wasn't	05:01	19 that information with you.
20	satisfied that we established whether the	05:01	20 Q. I'm allowed to ask the parameters of the
21	conversation was in fact protected by a	05:01	21 conversation. I'm not asking for the substance.
22	physician-patient privilege. So I am going to ask	05:01	22 I'm allowed to ask the details of the
23	some questions to develop the details surrounding	05:01	23 conversations that surround the conversation so
24	that conversation that will tell us that.	05:01	24 that I can evaluate whether I think it's a
25	A. And I'm not going to answer those	05:01	25 privileged communication or not.

84 (Pages 330 to 333)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

<p style="text-align: right;">Page 334</p> <p>1 A. I'm not going to answer your 05:03 2 questions. 05:03 3 Q. I'm going to make my record. 05:03 4 Did you talk to your doctor about Digoxin. 05:03 5 Have you spoken to your doctor about Digoxin in 05:03 6 the last 12 months? 05:03 7 A. I'm not going to answer these 05:03 8 questions. 05:03 9 Q. You're refusing to answer that 05:03 10 question? 05:03 11 A. I am. 05:03 12 Q. Have you spoken to your doctor about 05:03 13 this litigation in the last 12 months? 05:03 14 A. I'm not going to answer the question. 05:03 15 Q. Have you spoken to your doctor about 05:03 16 your engagement as an expert witness in the last 05:03 17 12 months? 05:03 18 A. I'm not going to answer any 05:03 19 questions. It was within confidentiality with 05:03 20 my doctor. 05:03 21 Q. Your engagement as an expert witness? 05:03 22 A. I'm not going to answer the question. 05:04 23 Q. Have you spoken to your doctor about 05:04 24 the effects of Digoxin and its uses? 05:04 25 A. I'm not going to answer the question. 05:04</p>	<p style="text-align: right;">Page 336</p> <p>1 THE VIDEOGRAPHER: The time is 5:07. 05:06 2 We are back on the record. 05:06 3 MR. ANDERTON: Dr. Bliesner, I have no 05:06 4 further questions at this time. 05:06 5 Unfortunately because we haven't had a 05:06 6 chance to review all the documents that you 05:06 7 produced because we have the outstanding -- 05:06 8 some outstanding issues, as much as I would 05:06 9 like to tell you that this is the final 05:06 10 session of this deposition, I can't give you 05:06 11 that guarantee. 05:06 12 THE WITNESS: I understand. 05:06 13 MR. ANDERTON: So if it is not, we will 05:06 14 in touch with counsel for the Plaintiffs to 05:06 15 make arrangements and they will be in 05:06 16 contact with you. 05:06 17 THE WITNESS: I understand. 05:06 18 MR. ANDERTON: We are going to keep 05:06 19 these binders. Phil, will you mark both of 05:06 20 these binders as the next exhibits as well? 05:06 21 And then here are the others. And they are 05:06 22 going to stay -- all of these document are 05:06 23 going to stay with Shook, Hardy, 05:06 24 Dr. Bliesner. And pursuant to agreement 05:06 25 with Mr. Kerensky, we are going to have them 05:06</p>
<p style="text-align: right;">Page 335</p> <p>1 Q. Do you take Digoxin, Dr. Bliesner? 05:04 2 A. I do not. 05:04 3 Q. Do you take any heart medications? 05:04 4 A. What do you mean by heart 05:04 5 medications? 05:04 6 Q. Dr. Bliesner, do you take any 05:04 7 medications for heart conditions? 05:04 8 A. Is blood pressure a heart condition in 05:04 9 your mind? 05:04 10 Q. If you think it is, say yes. 05:04 11 A. I've never really considered it a 05:04 12 heart condition. I considered it high blood 05:04 13 pressure. 05:04 14 Q. Other than your blood pressure 05:04 15 medication, do you take any medications for 05:04 16 heart conditions? 05:04 17 A. No. 05:04 18 Q. Does anyone in your family take any 05:04 19 medications for heart conditions? 05:04 20 A. No. 05:04 21 MR. ANDERTON: Off the record. 05:04 22 THE VIDEOGRAPHER: The time is 05:04 23 5:06 p.m. We're going off the record 05:04 24 briefly. 05:05 25 (Short break) 05:06</p>	<p style="text-align: right;">Page 337</p> <p>1 make copies and you're going to get back the 05:07 2 originals. And then we will get a copy. 05:07 3 THE WITNESS: Okay. 05:07 4 MR. ANDERTON: Okay. The court 05:07 5 reporter can keep a copy and then make a 05:07 6 copy. I'm sorry. The court reporter will 05:07 7 get a copy. 05:07 8 THE WITNESS: Okay. 05:07 9 MR. ANDERTON: And then we will get 05:07 10 copies as they provide us copies of the 05:07 11 transcript. 05:07 12 THE WITNESS: Okay. 05:07 13 MR. ANDERTON: Okay. Thank you very 05:07 14 much for your patience. It was a long day, 05:07 15 a long process. Thank you very much. 05:07 16 THE WITNESS: Same to you. 05:07 17 MR. ANDERTON: Mr. Kerensky. We're off 05:07 18 the record now. 05:07 19 THE VIDEOGRAPHER: The time is 5:09 p.m. 05:07 20 This concludes the videotape deposition of 05:07 21 Dr. Bliesner. We are off the record. 05:07 22 (Whereupon, Exhibits 155 and 156 23 were marked for identification) 24 (THEREUPON, the taking of the deposition 25 was concluded at 5:09.)</p>

85 (Pages 334 to 337)

David M. Bliesner, Ph.D.

Videotaped

February 18, 2011

<p style="text-align: right;">Page 338</p> <p>1 CERTIFICATE OF OATH</p> <p>2</p> <p>3 STATE OF FLORIDA</p> <p>4 COUNTY OF HILLSBOROUGH</p> <p>5</p> <p>6 I, the undersigned authority,</p> <p>7 certify that DAVID M. BLIESNER, Ph.D.,</p> <p>8 personally appeared before me and was duly sworn</p> <p>9 by me.</p> <p>10 WITNESS my hand and official</p> <p>11 seal, this 2nd day of MARCH, 2011.</p> <p>12</p> <p>13</p> <p>14</p> <p>15 _____</p> <p>16 PHILIP RYAN, RPR</p> <p>17 NOTARY PUBLIC - STATE OF FLORIDA</p> <p>18 COMMISSION # DD 988415</p> <p>19 MY COMMISSION EXPIRES: JUNE 28, 2014</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	
<p style="text-align: right;">Page 339</p> <p>1 CERTIFICATE OF REPORTER</p> <p>2 STATE OF FLORIDA</p> <p>3 COUNTY OF HILLSBOROUGH</p> <p>4 I, PHILIP RYAN, RPR, certify that I</p> <p>5 was authorized to and did stenographically</p> <p>6 report the foregoing deposition; and that the</p> <p>7 foregoing transcript is a true record of the</p> <p>8 testimony given by the witness.</p> <p>9 I further certify that I am not a</p> <p>10 relative, employee, attorney, or counsel of any</p> <p>11 of the parties, nor am I a relative or employee</p> <p>12 of any of the parties' attorneys or counsel</p> <p>13 connected with the action, nor am I financially</p> <p>14 interested in the action.</p> <p>15</p> <p>16 DATED this 2nd day of March, 2011.</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21 _____</p> <p>22 PHILIP RYAN, RPR</p> <p>23</p> <p>24</p> <p>25</p>	

86 (Pages 338 to 339)